Advancing Treatments for Post-Traumatic Stress Disorder
Hybrid Public Meeting
September 6, 2024 | 1–3:30pm (Eastern Time)

Transcript

Welcome

Susan C. Winckler, RPh, Esq, Reagan-Udall Foundation for the FDA

Susan Winckler:
Hello and welcome to those of you here in the room and those who are joining us virtually. I'm Susan Winkler and I serve as Chief Executive Officer at the Reagan Udall Foundation for the FDA. We are pleased to convene this public meeting on advancing treatments for post-traumatic stress disorder and to collaborate with FDA and other federal agencies.

For those of you who are new to the Foundation's work, we are the nonprofit, non-government organization created by Congress to help the FDA do more to protect and promote the public's health. One way we do that is by convening meetings such as this one to help the Agency (Food and Drug Administration (FDA)) share information and hear from stakeholders about important issues. These engagement opportunities help inform the Agency's work. Of note, however, we do not advise the FDA on regulatory decision-making.

Before we begin, I have a few housekeeping issues to assure that we have a productive and engaging meeting. Most of our speakers, and several attendees, are gathered here in the Foundation's Headquarters in Washington DC. We also have a significant number of virtual participants. For our virtual participants, a link to today's meeting materials can be found in the chat. And those of you in the room should have received materials when you checked in.

So, let's do a quick note about the agenda and a bit more on (that) housekeeping. Because of the size of the meeting, virtual attendees' cameras and microphones will remain off throughout the event with one significant exception. Those of you who were confirmed in advance to present stakeholder comment will be granted access to unmute and show video during the comment period. We are recording this meeting, and we'll post the recording along with the slide deck and transcript on the Foundation website reaganudall.org next week.

In just a moment, we will hear opening remarks from the US FDA and then turn to a discussion with leaders from several key federal agencies to explore their activities in addressing post-traumatic stress disorder. Then, we will move to a critical part of our meeting, providing an opportunity for members of the public to share perspectives and experiences. I thank everyone who offered to provide public comment. We received so much interest and regret that we were not able to accommodate everyone's request to speak, but each of you has the opportunity to provide input via email. Please email comments to PTSD@reaganudall.org. We'll include a recap of both the presented and the written comments in our event summary.

Now, the following information is very important for our virtual commenters. So sorry for the tedium here, but this will help later. We have 30 individuals identified for virtual and in-person, and each has up to three minutes to speak. We will begin with those of you who are joining virtually and proceed in alphabetical order by last name.

I will provide a rolling list of three speakers, so you should hear your name twice before I call on you to present your remarks. For example, we will begin public comment by announcing that our first three commenters will be hypothetically Jane A, Jane B, and Jane C. I will then a call on Jane A to present her remarks. When you hear your name For the first time, use the raise hand function so that we can find you in the meeting. When you hear your name the second time, turn on your camera and when the speaker before you concludes their remarks, please unmute yourself. Our producers will highlight you when you are introduced to speak.

Our in the room commenters will use one of these podiums. I will follow the same procedure of announcing the queue of speakers. Please move to the stairs by the stage when your name is first called, and move to the open podium when your name is announced for the second time. You will speak from that podium when I introduce you.

And now, take a deep breath because we have completed the tedium of preparing for our meeting today and are ready to move to the incredibly important substance of this topic. Much of our discussion today will include the research and experience of veterans with post-traumatic stress disorder (PTSD). But we should remember that PTSD is not selective in its impact. Veterans comprise a large group who experience PTSD, but the disorder affects many others as well. Those who have experienced abuse or assault, those who have lived in other dangerous environments and those who have witnessed, responded to, or experienced accidents, disasters, and other traumatic events. Our efforts today are intended to explore and help all experiencing post-traumatic stress disorder.

I'm going to turn the substance over first to Dr. Bernard Fischer to provide opening remarks. Dr. Fischer serves as the deputy director of the Division of Psychiatry in the Office of New Drugs at FDA's Center for Drug Evaluation and Research. Dr. Fischer….

Opening Remarks
Bernard A. Fischer, MD U.S. Food and Drug Administration, HHS

Bernard A. Fischer:
Thank you. Good afternoon. As Susan mentioned, I'm Bernie Fischer. I'm the deputy director for the Division of Psychiatry at the US FDA. Prior to coming to FDA, I worked as a psychiatrist in downtown

Baltimore and also at the VA hospital system, and I was also in the US Navy, I'm a veteran. I was deployed as a psychiatrist to the Role 3 hospital in Kandahar, Airfield Afghanistan.

I'm going to talk a little bit about PTSD as an introduction to our talks today. I'm going to talk a little bit about the history of PTSD, then a little bit about what we know now and then moving forward.

So PTSD wasn't formally recognized as a mental health condition until 1980 with the year Diagnostic and Statistical Manual for Mental Disorders Edition 3. And that was largely in response to advocacy from veterans groups. It's been known by other names throughout human history. In the 1700s, it was called nostalgia. It was called soldier's heart in the American Civil War, shell-shock and World War I, and battle fatigue in World War II. But the symptoms of PTSD can be seen in the Greek tragedies and in plays by Shakespeare so the symptoms predate this.

Just as an example from one of Shakespeare's plays, this is from Henry IV Part I, and just in case you're not familiar with the play, it was written in the late 1500s. And the character that is described in this passage here, Harry Percy, he fought a number of wars for King Henry and now, he's returned home and he's joining with some of the nobles that are opposing Henry's reign. So his wife, Lady Percy, has noticed that since he's come back, he hasn't been the same. So I'm not going to read the entire passage, but I want to select some quotes here that really highlight some symptoms that could be consistent with PTSD.

So she says, "Oh my good lord, why are you thus alone?" So he's isolating. He's banished her from his bed. He has decreased libido. She notices that he has physical complaints. He talks about his stomach, he talks about poor sleep. She notices that even when he's sitting there by himself, he startles. He has this increased startle response. And then, she's also noticed that he has this melancholy, this depressed mood. When he does sleep, she hears him crying out in his sleep saying commands like he's on the battlefield. And she's also noticed that when he has this, he has these beads of sweat on his brow. He has this autonomic arousal. So looking at this passage here, you see what looks very much like PTSD.

Not all of the historical references to PTSD are from battle or combat. In the late 1800s when we were increasingly moving to rail transit, there were actually terrible train crashes that would happen. And people who would survive the crashes, even without a physical injury, they would often present after the crashes with irritability, with anxiety, with problems sleeping. And the physicians at the time, they said, "Well, we don't know what to make of this. We don't see any physical injury they look, okay, so it must be the process of moving so fast on the train and this abrupt stop has done something to their spine, and that's what causes these symptoms." And so you had this diagnosis of *railway spine*.
And the illustration here is from a Staplehurst accident, a terrible train wreck that happened in 1865. And actually a passenger on that train at the time was Charles Dickens, the author, and he was actually in the car that's hanging off the bridge there. When he was rescued from that car, he went around trying to help the injured and he saw some terrible things that had happened in that accident. 10 people were killed. After the accident, he had nightmares, he had problems sleeping. He's documented this in letters that he's exchanged with people and also his children have written about how he was after that train crash. He actually avoided trains after that. He used to travel continental Europe on trains, but after this accident, he restricted his travel. And when he did have to take a train, he would often exit the train miles before his stop and just walk because he couldn't take being on the train.

So switching gears a little bit to talk about PTSD now, there is a preponderance of women who get the diagnosis compared to men, but that may be due to a number of different factors including risk factors

for traumatic events themselves. When you look at combat veterans and PTSD, it seems like there's a pretty stable percentage of people who get diagnosed with PTSD regardless of the conflict. PTSD, in addition to the symptoms that someone can have which impact them and their family, it can be a risk factor for a number of other things like suicide, housing instability, other health problems, physical health problems, and premature death. So it's clearly a huge public health concern.

When you look at PTSD, some of the symptoms that you see in people seem to be an exaggeration of a normal response to threat. There are some effective talk therapies that can be used for PTSD to try and decrease that perceived threat, but those therapies can be really difficult to do. They're time intensive, and it's especially difficult when you have to talk about the trauma when everything about you is saying to avoid that.

There are approved drugs for PTSD, but there's only two and they work in this similar mechanism and they provide symptomatic relief and they don't work for everybody. There's a large percentage of people with PTSD for whom the drugs just don't appear to work as well. So it's clear to FDA and the federal government at large that there is an unmet need for safe and effective therapies to treat PTSD. So talking about moving forward a quick check of clinicaltrials.gov where people have to post the clinical trials they're doing, if you look at PTSD, there's 477 trials that are either currently recruiting or getting ready to recruit. So out of those trials when companies are looking to market a drug, they can engage directly with the FDA, and we have various programs that can help them get their drug...help them with their development program.

So there's breakthrough therapy designation. If we think that the drug represents what could be a meaningful advantage over what's already approved and being used, we can grant this breakthrough therapy designation, which enables the FDA to have a lot more communication and a lot more guidance with the programs to help them develop drugs. When a company thinks that they're ready for a marketing application, if they submit something, we can grant them a priority review, which means that really, it's all hands-on deck and we try and get an answer about whether the drug is marketable ahead of our normal schedule.

There are similar programs that we use for devices and just to highlight a specific device, the Nightware device, it received a breakthrough device designation and then was cleared by the FDA for the temporary reduction of sleep disturbances related to nightmares associated with PTSD.

So thinking about PTSD, you often hear people talk about military PTSD versus civilian PTSD. And I think that's somewhat of a misnomer because military PTSD can encompass a variety of traumatic events including vehicle accidents and personal assaults. It's not all combat.

We might be getting closer to something that's a meaningful distinction when we talk about combat versus non-combat PTSD, but I propose that it may be better framed as PTSD to a single traumatic event, something like a car accident or an assault versus repeated trauma in an ongoing stressful environment. Something like combat or intimate partner violence.

Our advice from FDA when developing drugs for PTSD, one piece of advice is to make sure that you have a good demographic mix. We want to see trials that really represent the makeup of the United States. We also want to see that in the trials there's a representation of what we see in people with PTSD. So we want to see a range of time since the traumatic events. We also want to see a variety of events. We want to see people who've experienced a single event, people who've experienced repeated trauma.

In developing drugs and devices, I think we're at a great point scientifically in human history, where we have a number of things that we can call on to influence how we understand PTSD and help us design therapies. So when we talk brain circuitry, there's not good animal models for most mental health conditions, but this response to threat circuit that I've talked about can be modeled in animals. Biomarkers are being studied for a number of psychiatric illnesses, and these biomarkers may be able to help us determine who is at risk for developing PTSD. It, maybe in the future, can help us diagnose PTSD, maybe even be used as an endpoint to help us determine whether people with PTSD are responding to a certain treatment.

So, as we look forward, I think another big component of what's influencing us at this time is being informed by people who don't get PTSD. Studies of resilience in people who've been exposed to traumatic events, but then don't wind up developing PTSD. What can they teach us about how to treat people who develop PTSD?

So those are my comments to introduce the topic, kind of summarizing a little bit from the past where we are now and some directions for the future, but I think there's good reason to be optimistic, and that's a segue to our federal panel.

Susan Winkler:
Great. Thank you so much, Dr. Fischer.

We'll move from that grounding to hear from a variety of sections of the federal government about their work in post-traumatic stress disorder.

We have already on the stage, and I hope that we have virtually, our final panelists with representatives from the US Department of Defense, from the Department of Health and Human Services and from the Department of Veterans Affairs. So, could I get confirmation that we have Dr. Katz online? And if we do, could we show her visually because then our panelists can all interact. And I will just note for you, panelists, if we all stare at the monitor, then all the pictures look like we're looking down and we're not engaged with each other. So just a tip for that component.

So let's jump directly into the conversation as we wait for Dr. Katz to appear on the screen here in the room. I'm going to start, Dr. Gandotra, with you.

There we go. Hello, Dr. Katz, welcome.

But let me turn, as I said, to Dr. Gandotra. Tell us about your work in your role as Chief Medical Officer at SAMHSA, or the Substance Abuse and Mental Health Services Administration, within HHS that relates to PTSD. And I am going to call you Dr. G after this.

Federal Partner Discussion

Neeraj "Jim" Gandotra U.S. Food and Drug Administration, HHS:
Perfect.

Susan Winkler:
It should go on. Yeah, you're live.

Neeraj "Jim" Gandotra:
Okay, great.

First of all, thank you very much for the opportunity to discuss some of SAMHSA's work. Certainly, we are invested and thank you to Dr. Fischer. Thank you for the invitation and the enlightening introduction.

As mentioned already, PTSD affects a significant portion of the population, and yet we also know that despite that number individuals and particular communities have experienced trauma at even higher rates. And yet, we're just now beginning to understand the unique factors that promote prevention and resiliency, as previously mentioned. And there's a lot of information that we hope will be gleaned in the upcoming years that will promote an evidence-based approach towards treatment of PTSD.

Certainly, we know that SAMHSA, HHS, and our federal partners have understood that there are multiple angles of approach when it comes to addressing PTSD. Certainly, social determinants of health, as well as comorbid conditions that emerge later, such as substance use disorder, which occurs at a very high rate for individuals with PTSD, has been a focus of SAMHSA. And certainly, we want to provide resources for evidence-based interventions that balance not only the therapeutic efficacy, but also the risks that are associated with those interventions.

But at SAMHSA in particular, our bread and butter is treatment service grants and technical assistance. And I'm going to speak a bit about those. And really it's related to our strategic plan, which has primarily five goals. The first one is very much related to everyone in this room and for the American people, it's really to promote the prevention of suicide, and that really speaks to resiliency and the intersection with PTSD. Of course, we have grants for mental health and substance use disorder treatment services as our other priorities as well as behavioral health integration.

But another strategic priority that really intersects with this that's already been mentioned has been resiliency. And we really do want to promote the resiliency within children and families, particularly those who are affected and experiencing trauma. And of course, our workforce. We can't do anything without expanding the workforce competencies to ensure that we're able to appropriately address this issue among several others. And our strategic plan is actually underpinned by the principles of equity trauma-informed approaches, a commitment to data and recovery. We feel that all of those cross-cutting principles have to be addressed in everything we do. And addressing PTSD is no different.

I would like to highlight a few of SAMHSA's programs that really do address this. And when I get into that, the first one I want mention is something that should be available to everyone any given day 24/7. And that's the 988 Crisis Lifeline. I can say I've personally used it and tested it for my patients. The follow-up is great. They've been able to be a tremendous resource and particularly, for under-resourced communities who at least link individuals to care.

And then, I'd like to at least highlight our mental health block grants. We've invested over a billion dollars into mental health services under which PTSD is not only addressed, but it's screened for it at admission for every enrollee that our grantees serve. And there's also a set-aside for crisis services that is not only permitted but encouraged for every state. So we feel like this is just the beginning point of

that investment. And really the partnerships with the programs in the community are where the real work gets done.

And that sort of leads me to our recast program, which is related to resiliency for communities experiencing stress and trauma. And this particular program is for technical assistance for providers. I can say that since its inception in 2016, it has trained over 100,000 mental health workers and community members, and we can say for sure that we've also probably served over 950 partner organizations with this training. We believe that that also speaks to the principle that while we can sit in DC and come up with policies, it's the programs out in the community that implement those policies and we don't know what we don't know, and we have to get the feedback from those grantees, from those individuals who are serving the communities that we hope will benefit from our resources.

We also have services, technical assistance for veterans. We have our for military veterans and their families, ATA Center. I would encourage anyone who's interested to take a look at the resources there as well.

And then it was mentioned that PTSD also can be initiated, or it can emerge in childhood. And we have our National Childhood for Stress and Trauma Network, and this program is divided into several parts, but the initiative and the network have served over a million people. And I can say that the training for this has been ongoing. We've received a tremendous amount of partnerships in the community. I think we have probably over 2 million professionals trained at this point through that network, and it provides resources for a collaboration because that's really what this is about, is a collaboration among our federal partners and among the community.

Finally, I'll just mention that we also have our certified community behavioral health clinics. That coupled with the block grant provide services irrespective of the ability to pay. So even if someone has financial difficulty, if they can get connected either in person or virtually, that services will be offered. So I've spoken a bit about treatment and prevention. And prevention really is critical for the emergence of PTSD, and we have some tools in the toolbox. Certainly, we could utilize more, and the interest that we have is ensuring that whatever tools are in the toolbox are appropriate for that particular individual and that community. And in that light, I think that we work with the partnerships here to ensure that we're taking an evidence-based approach that is not only thoughtful, reliable, and trusting and worthy of the trust that's been instilled in all of us by the American people.

Susan Winkler:
Dr. G., thank you. And I think if we all heard you correctly, you walked us through some of the resources available in an emergency, then the efforts to underscore treatment that's available and in prevention. So it's helping us better understand the SAMHSA space, thank you.

I want to turn to our virtual guest and specifically hear about the work of the Department of Defense. Dr. Elyse Katz works as a contractor supporting the Defense Health Agencies, PTSD Drug Treatment Program, Dr. Katz, I want to make sure that we can hear you and we welcome your thoughts on this space.

Elyse Katz, Department of Defense:
Can you hear me okay?

Bernard Fisher:
A bit. If we could turn it up in the room. Go ahead. [inaudible 00:28:50].

Elyse Katz:
Let me know, is this better?

Bernard Fisher:
Excellent. Yes.

Dr. Elyse Katz:
Okay, great. Thank you so much for having me today. As mentioned, I am a DoD contractor and do not speak on behalf of the DoD or the US government, but I was very pleased to be here today to talk about a large, innovative Defense Health Agency clinical trial that we hope will yield the robust data necessary to support the development and delivery of new drug treatments for PTSD.

In order to ensure that our nation's military service members are healthy, functional, and performing at their highest levels, the Defense Health Agency has stood up a PTSD drug treatment program, which I have had the honor of supporting the last eight years.

So I'm seeing some feedback here that there might be some issues with my audio. Let's see, try this.

Susan Winkler:
We can hear you, it's okay.

Elyse Katz:
This better? Okay, I just want to make sure.

Susan Winkler:
There you go. Yep, you're fine.

Elise Katz:
Okay, great.

So the objective of our PTSD Drug treatment program is to develop drugs that can effectively treat PTSD in our service members and veterans. Whether that is by providing high quality evidence for or against the use of existing drugs. Or by partnering with private industry to de-risk and otherwise support industry's clinical development programs to increase the chances of FDA approval for new drugs.

Despite 150 clinical trials testing over 58 different drugs or drug combinations to treat PTSD in the last 35 years, as we heard earlier, there are still only two FDA approved drugs that do not show high levels of efficacy, especially in our military population. We believe that much of the failure in this area is due to yet to be fully understood the clinical and biological differences between individuals with PTSD as well as…

PART 1 OF 5 ENDS [00:31:04]

…differences between individuals with PTSD as well as due to a siloed research approach in the area that includes the conduct of small one-off studies run by individual investigators or companies with unique

testing procedures and endpoints. So to address this, the PTSD Drug Treatment Program has partnered across academia, industry, and with our government colleagues to design and conduct the military and veterans PTSD Adaptive Platform Clinical Trial, or M-PACT.

Although platform trials have been increasingly employed in other disease areas, like oncology and across Covid, the M-PACT is the first platform trial in psychiatry. This type of trial establishes a common infrastructure for testing multiple drugs and therefore is a more efficient use of resources compared to the more traditional approach of testing one drug at a time in separate trials. The M-PACT study design is unique in that it allows for sharing of placebo data across treatment arms, which decreases the total number of subjects that we need to enroll. And second, the test, it allows for testing of multiple drugs simultaneously and sequentially, where drugs will cycle off the platform based on accumulating evidence that indicates the probability of either success or failure in decreasing PTSD symptoms.
The M-PACT is currently testing two drugs for the treatment of PTSD in this FDA-regulated phase II master protocol and a total of four drugs including, SLS-002, which is an intranasal racemic ketamine formulation, have been selected for testing thus far. Importantly, [inaudible 00:32:55] mentioned earlier, we also recognize the need for biomarkers in this area. So we've incorporated the collection of different types of biomarker data as well as a breadth of different clinical assessments that will be used to tease apart PTSD's heterogeneity with the goal that both the biomarker and clinical assessment data may lead to a precision medicine approach to treatment where the drugs that will be prescribed in the future will be based on what is likely to be most effective for each individual. With this platform trial and the precision medicine approach, we really hope that to be able to confirm what we know and what we don't know about PTSD and really to drive future drug and diagnostic development efforts.

To find out more about our study, the M-PACT study, please that our study website at PTSDclinicaltrial.org, which will actually be going live next week, and on this website, patients can express interest in enrolling in the study. Industry partners can respond to a request for information about investigational products they would like to have considered for testing in the M-PACT, and entities interested in participating as a clinical site can reach out to us.

Just lastly, I'll mention that during the public comment segment of today's meeting, my colleague, Major Erin Wolfgang will highlight some different approaches specifically related to psychedelic research within the DOD. You'll also hear more from CLS Therapeutics regarding the intranasal ketamine product that I mentioned earlier. So thank you very much for listening and for your time. I'll turn it back over to you the rest of the panel.

Susan Winkler:
Thank you, Dr. Katz, and I understand there may have been some audio issues on the transmission, but we'll make sure in the recording that's posted that we capture all of the insight that you just shared, that took us from some of the grounding in Dr. Gandotra's remarks about the work that's being done to use current interventions to the research that DOD is pursuing to help us develop better and have better interventions to use in PTSD. So, thank you so much, Dr. Katz.

So let's turn now to the Department of the Veterans Affairs, and we have two of you to present today, which is fabulous. Dr. Paula Schnurr is Executive Director of the VA National Center for PTSD, and Dr. Miriam Smyth is the acting director of the Clinical Science Research and Development Service, and acting director, Brain Behavior and Mental Health. I'm going to turn to the two of you for the oversight of the work and activity of the VA, both in providing care and in generating evidence about potential treatments and interventions. I'll let you two decide who's going first. Perfect.

Paula P. Schnurr, U.S. Department of Veterans Affairs:
Thank you so much. I'm so pleased to be here today to talk about VA's efforts to advance the care for veterans with PTSD. There's three parts to what I want to say. First, just to give you some context about VA, then to talk more about PTSD treatment, and then a little bit about the future of where I think we need to be going with PTSD treatment.

Our top priority in VA is providing the safest, most effective care available for our nation's veterans. We are the largest integrated healthcare system in the country. Last year we treated 5.7 million veterans at over 1300 sites of care. The number of veterans with a mental health disorder seeking mental health care in any given year has doubled since 2006, so that now about 30% of our enrollees will receive mental health care in any given year. So we build our services around the assumption that one out of three of our patients will need mental health care.

Our approach prioritizes recovery through evidence-based treatment across a continuum of care, from self-help apps to outpatient care, residential care, and acute inpatient care. One way that we promote evidence-based practice is by collaborating with our Department of Defense partners in producing clinical practice guidelines for conditions that are relevant to our population, mental and physical health conditions. We have a guideline not only for PTSD, but depression, insomnia, suicidal behavior, substance use, and other conditions in the mental health space. Now on to PTSD. This is an important priority for us because last year just over 14% of our veterans who received care had a diagnosis of PTSD. It's a lot of people.

VA has a long history of providing PTSD care. In 1989, we stood up specialized outpatient and residential treatment programs. We now have 128 outpatient programs in 43 residential programs with experts in PTSD care. All VA facilities have either a specialized outpatient program, or at smaller facilities they will have a PTSD specialist. Also in 1989, the National Center for PTSD, which I lead, was founded by VA to conduct research and promote education on PTSD. Through the National Center we have helped advance the assessment and treatment of PTSD through developing gold standard methods for assessment, questionnaires, and interviews through groundbreaking research on medications, psychotherapy, complementary and integrative practices such as yoga. And we also have developed a number of self-help apps. In addition, VA has supported research and education by creating other centers of excellence that also focus on PTSD.

Now, education for our providers is a key part of our strategy. Beginning in 2007, we initiated a national treatment training program in evidence-based psychotherapy for PTSD using two of the most effective treatments: prolonged exposure and cognitive processing therapy. We require that all VA medical centers offer these treatments now, and many VA providers also have, many VA sites rather, have providers who are trained in additional evidence-based treatments, so that we can support our goal of providing evidence-based care.

I'd like to close by just saying a few words about where I think we need to be going with PTSD treatment. First of all, PTSD is a treatable condition. I think sometimes we don't hear that, it is a treatable condition. There are effective treatments that work well for a lot of people, although not everyone has a satisfactory response. There's room for improvement. And this is not a PTSD problem, this is a mental health disorder problem. In fact, the psychotherapies for PTSD work as well as the psychotherapies for depression.

That's why VA is committed to supporting innovations in care for PTSD and other mental disorders. And one avenue is psychedelic medicine. At VA, we are continuing to prepare for future potential clinical implementation of psychedelic treatment, primarily by supporting and conducting research on medications such as MDMA and psilocybin for treating PTSD and depression. And I'm now going to turn things over to Dr. Smith to talk more about that research and other innovations in VA research.

Miriam J. Smyth, U.S. Department of Veterans Affairs:
Thank you, Dr. Schnurr. The Department of Veterans Affairs, the VA is indeed committed to improving the health of our veterans by advancing innovative research in PTSD. For almost a century now, the VA Research and Development program has been improving the lives of veterans through research across the translational spectrum, from basic science to implementation science. We are proud to be uniquely dedicated to addressing the research needs of our veterans. I can speak to that personally, having been working in VA research now for 29 years. Our work occurs at 105 medical centers nationwide, and currently we have over 140 active research projects in PTSD, and our financial commitment to those projects is over $230 million. Veterans play an integral role in our research program. Thousands of veterans volunteer each year to participate in VA research studies to address their own health challenges, but also to help their fellow veterans.

Today I'm going to give three examples of our innovative PTSD research. First, the PTSD Psychopharmacology Initiative. Secondly, the Million Veteran Program. And then I will follow with research into psychedelic assisted therapy.

The VA PTSD Psychopharmacology initiative has been focused on accelerating the development of better PTSD medication treatments for veterans. The initiative began in 2017 with a multi-pronged approach, which included broadening our psychopharmacology clinical trials workforce. Today we have 14 active clinical trials under this initiative, the first of which will end this coming year, and we're very much looking forward to seeing those results being published and to moving appropriate discoveries into clinical care for veterans.

The second example, the Million Veteran Program, is a novel national research program looking at how genes, lifestyle, military experiences, and military exposures affect health and wellness of veterans. This is one of the largest research programs in the world that is focused on studying genes and health.

Over 1 million veterans have now enrolled in MVP. Actually, it's 1,043,000 today. And MVP PTSD studies have found genes related to re-experiencing traumatic memories, a common symptom of PTSD. They have also advanced our understanding of the relationship between PTSD, traumatic brain injury, TBI, genetics and dementia, and have confirmed that both PTSD and TBI are risk factors for dementia. By knowing which genes are involved in PTSD, scientists may be able to repurpose drugs that are known to interact with these genes and that are currently approved for other medical treatments. So, these MVP studies give scientists new and exciting avenues to pursue.

My third example, VA research efforts related to psychedelic assisted therapy. In January of 2024, we published our first request for applications for psychedelic research. This means that for the first time, we provided the opportunity for VA researchers to submit proposals, requests for funding on psychedelic research through VA's intramural research program.

The opportunity we offered is focused on testing MDMA and psilocybin in combination with psychotherapy for the treatment of mental health conditions, including PTSD and depression in

veterans. Before our funding announcement, some psychedelic studies were conducted at a handful of VA facilities across the country. VA researchers were involved in those studies, but these studies were funded by external organizations and involved a relatively small number of veterans. We received the first wave of applications in response to our funding announcement early this summer. Scientific peer review panels comprised of research experts from across the country, both VA and non-VA researchers, have now reviewed and scored those applications for scientific merit and feasibility. Decisions related to funding will be made this fall.

As studies are initiated, psychedelic studies, VA medical centers will locally announce the opportunity for veterans to enroll in these trials. In the meantime, we remind our veterans for their safety that they should not use psychedelics as part of a self-treatment program. In closing, as you've heard, we in VA are highly committed to improving the health of our veterans by conducting innovative research to improve PTSD treatment in support of those who have sacrificed so much for this nation. Thank you.

Susan Winkler:
Yes, thank you Dr. Miriam [inaudible 00:46:24] Smyth. I want to underscore, I think I just heard the power of 1,043, 000 veterans contributing to the research in this space, which we combine it with the clinical trials work that Dr. Katz referred to, I think is at a minimum that and that research is potentially exciting.

All right, let me turn back to the Department of Health Administrative Services, and particularly the Food Drug Administration. So Dr. Sokolowska, when I think about the role of the FDA in healthcare, you review the evidence generated by researchers and product developers about potential treatments. What should we know about the agency's role, particularly from your vantage point as Deputy Center Director for Substance Use and Behavioral Health in FDA's Center for Drug Evaluation and Research?

Dr. Marta Sokolowska, U.S. Department of Veterans Affairs:
Well, thank you Susan, first of all, and thank you to the Reagan-Udall Foundation for organizing convening this meeting on this very important topic--important to us and important to so many people both on this panel and so many people who want to make comment on this issue, and so many people that are here in this room. So thank you very much to you and everybody who wants to participate. We really appreciate this support for this important topic because in order to address it, we really have to even better understand the disease itself, the unmet need, and how can we use that for support facilitating development of new treatments and approving of new treatments for this disorder.

I am very grateful for having the federal panel, because FDA alone cannot solve the problem. Yes, we are reviewing the evidence, but as we've heard, there is a lot of work ongoing, support for patients as well as development of new treatments. And only by working together we can assure that we are going in the same directions, we have the same goal and the platforms, the innovations that is happening is really aligned and streamlined so we can really get the results that we all want faster. And I'm really looking forward to hearing the comments from the public because it's so critical for us to understand the impact on patients, the impact on the caregivers, but also hearing from the clinicians, from the researchers and the sponsors. So again, thank you very much.

But to your question regarding FDA responsibility, as you mentioned, FDA responsibility is to ensure the drugs are both safe and effective. And in order to approve a drug we must determine that the research and the data submitted by sponsors show that the drug truly is safe and effective for the intended use.

And this is the standard that we use for approving of all drugs. And we already approved two medications, as mentioned by Dr. Fischer earlier, for treatment of PTSD.

But as Dr. Fischer also mentioned and others, that is still the great need. And FDA, I do believe has been leaning in into trying to help to address this issue. So for instance, FDA understanding the unmet need and reviewing preliminary data, we have granted breakthrough designation both for devices and for drugs as potential treatments for PTSD and as Center for Drugs, we granted, for instance, a breakthrough designation for [inaudible 00:50:10] amphetamine for treatment of PTSD as reported by sponsors.

Within the Center for Devices and Rare Radiological Health, there have been several devices more recently that have been received marketing authorization for treatment of PTSD. So I'll just mention few. The first one actually mentioned by Dr. Fischer as well. Nightwear is a digital therapeutic intended for temporary reduction of sleep disturbance related to nightmares in adults 22 years or older who suffer from nightmare disorders or who have nightmares for PTSD, and that was granted, the marketing authorization was granted in November of 2020.

But it didn't end at that, together we have additional devices such as, another example is Freespira. It's a biofeedback device intended to be used as injunctive treatment of symptoms associated with panic disorder and PTSD. And that marketing authorization was granted in August of 2018. And more recently, PRISM, which is a software as a device, which is to be prescribed for treatment of symptoms of PTSD by clinicians as an adjunct treatment to standard of care. This software as a device received marketing authorization of February of last year (2023). So, it's even more recent.

Again, these are just few examples of products that have been reviewed and approved or authorized. As I mentioned, we are very much engaged. We are very excited about the new developments in the platforms and in the treatment profiles, how we are approaching these disorders. And we are really looking forward and hoping that it all is going to help us to have effective, to have evidence to hopefully approve more treatments and more devices soon.

Susan Winkler:
Right. Great. Thank you Dr. Sokolowska. It's always helpful to remind us of the agency's role in reviewing that evidence so that we provide interventions that have demonstrated the ability to help individuals.

So we're going to finish our tour of federal agencies and then I'll come back to each of you for a quick comment at the end. We'll finish it.

Dr. States, we're going to finish with the Office of the Assistant Secretary for Health at HHS. What should we know about the PTSD activity from your role as acting director of the Office of Science and Medicine, and Chief Medical Officer to the Assistant Secretary for Health?

Leith J. States, Substance Abuse and Mental Health Services Administration, HHS:
Thank you, Susan. Good afternoon everybody. Thank you so much for the invitation from the FDA Team. It's been a great pleasure to participate in these touch points with the outside world that I think are really valuable and have had tremendous impact in what I've seen from the FDA and what I've seen in some of my federal colleagues on this panel. So your presence here, either in person or online, it's very important, and thank you for making this a priority on a Friday.

So, like Dr. Fischer over there, I am also a Navy Medical Corps alum. And I had the distinct pleasure of serving on active duty with the Marines during my operational time and did a couple [inaudible] with him down range. So the things we're talking about in terms of not just the theme of PTSD doesn't happen in isolation, but the fact that there are a lot of contributors that aren't going to be solved in this room today or by a single drug…drug approval application, it is not lost on me, either personally or as a provider having had contact with plenty of corpsmen and Marines over time.

So, the one thing I wanted to think through, not what would be the party line HHS responses I could give you, but what might be of substance and worth to this group on Friday afternoon to make it worth you all sitting in those chairs. So, I'll hit a few items, but if I riff a little bit, just go with me.

So the first thing for me is that, I just alluded to it, it doesn't happen in a vacuum. And this gets to the point of it's not just the comorbid mental health and behavioral considerations, although the complications of having concomitant SUD along with depression, anxiety, and along with a history of generational trauma or food insecurity or economic inability to attain employment, having physical insecurity, lack of transportation, lack of internet, lack of access to digital devices, these are all things that contribute to that baseline level of stress and inability to comply with a treatment regimen that very well may be founded on a good sound base of evidence from the DSM or other sources, but because of those other considerations, they're not going to be able to get the full effectiveness of the SNRI, the SSRI, the EMDR, the PE, or prazosin even, if we wanted to go down some of the older methods.

So, there's no shortage of things, I think, that bring us to a common understanding around the complexity of this issue. And that's not lost on us at headquarters at HHS, which brings me to kind of the landscape or the way I like to view that relative lack of innovation in this space. It's not just that we need to get more tools, but we need to learn how to use adequately and respond to the environment we're currently operating in. How much right do we have to take new tools if we can't even use the ones we have available to us? I'm not saying, "Oh, let's not do anything on drug approvals and psychedelic [inaudible 00:56:05] therapy is a bad idea." I fully think there's promise, safety signal, and there is a place and purpose at some point based on development of evidence and doing things in that concerted effort with shared understanding around what merits safety and efficacy.

But that said, that gets me to the other point of we also are cognizant of the fact that not unlike any other point of life, whether this is in health, public health, outside world, there is no silver bullet. And the hard work of getting to the delta of change is what's partly taking place here today. Because we all have, and I'll acknowledge all of you in the room, we all feel some type of way about the decision that came out some time ago. And that's okay. That's all right. We're all big kids in the room and that's okay. For me, it's indicative of a fact that we're pushing forward and we're stressing the system and we're doing things in a way that marches us forward in an incremental way. Now granted, there might be some dissonance around what we thought were appropriate levels of evidence for this or that, but regardless, at the end of the day, I see opportunity.

And the opportunity I think is not just in understanding that the solution is not just in an NDA and FDA sharing burden alone here, but it's seeing the opportunity around what's been developing in concert with you and concert with Congress and leveraging the NDAA to increase funding with VA and DOD to increase the opportunities for representative data, increase the opportunities for novel clinical trial design, increase the time needed to adjust to what is a rapidly evolving approach to randomized clinical trials, and what that means for us in terms of doing our due diligence to protect the American people.

So I think that there's a lot of nasty, messy stuff in there, but at the end of the day, we're moving forward. And although we may want to see different speeds happen, I've been very encouraged, in my role at least... And that's me being a couple levels removed where I don't have to receive the direct hits from anybody. But it's been really encouraging to see and work alongside a lot of the friendly faces I see in this room and certainly the ones online. Let's see. Got a minute, 20. Okay-

Susan Winkler:
Well, that's what everyone has, so you've got 30 seconds.

Leith J. States:
Fair enough. All right. Okay. So two last things. One of the coolest parts here...this is not the first time we've met. Us as federal colleagues and panelists here and the ones online, we've met before. Which is I think really an excellent stomp. A foot stomp, take away--something I wanted to reiterate is that in large part because of the action of you all here and folks online, it's creating that demand signal for us to increase our degree to collaborate together, which I guess that's a way of saying thank you.

The last thing I'm going to say is that in terms of opportunities to pivot towards, where it's not just on us to do what we can with clinical trials and new drug applications, is to acknowledge the actual landscape we're operating in from state, local, tribal, and territorial governments. Because they're moving forward with state programs and there's an opportunity to protect public health and public safety there that is, to this point, not being coordinated well on. And the best way I see that happening is through better capture of data, collaboration, interoperability.

And with that, I just want to take one last foot stomp and say thank you again for this venue, for this panel, for what I know there are going to be great comments to come.

Susan Winkler:
Absolutely. Thank you, Dr. States. And you remind us that we are learning. In all of these steps, whether they're completely forward or partially forward or where we don't have as much forward movement as some might have wanted, we are learning, and that learning can help and help advance the work here.

All right, I promised you all that you would get less than a minute to provide a final word. And because I will be rigorous in the three minutes for public comment, I'm going to be rigorous on our less than a minute for each of you. So I'm going to go in the following order. Dr. Schnurr, Dr. Smyth, Dr. States. So Dr. Schnurr, fire away.

Paula Schnurr, U.S. Department of Veterans Affairs:
Yikes. I hope that doesn't count. I began studying PTSD in the 1980s just after the diagnosis was introduced. And it was a very controversial diagnosis. Many people didn't even think PTSD was real. And in terms of treatment, we thought PTSD was chronic and that what we needed to do was help people cope with their symptoms. That was then, this is now. We now know PTSD is a treatable condition. And that furthermore, as you saw some data, 6% of the US population will have PTSD at some point in their lives. It is a real diagnosis.

More importantly, with respect to treatment, we have effective strategies that work well, as I said, for many people, but there's room to improve these treatments. And I think as much as we're doing additional discovery of new treatments, taking what we have and making them better is certainly possible. Thank you.

Susan Winkler:
Brilliant. Dr. Smyth, Dr. States, Dr. Katz. Dr. Smyth?

Miriam Smyth:
I'd like to follow up on the idea of improving treatments and refer back again to a connection with the Million Veteran Program. I wanted to mention that there is a new opportunity that has been rolled out under the Million Veteran Program, a mental health survey. And I mention this because our veterans have been so committed to the Million Veteran Program and the data we are gathering from them are proving to be so valuable and we know will really will really-

PART 2 OF 5 ENDS [01:02:04]

... proving contribute significantly to research in upcoming years. That's a program that is focused specifically on mental health and substance abuse in veterans and it's called MVP MIND. Mind referring to Measures Investigating Neuropsychiatric Disorders. I will mention that the initiative is in early stages and right now we have staff members at five VA facilities. We already have collected almost 1,300 surveys and further expansion is planned, which really will contribute ultimately to our knowledge base. Thank you.

Susan Winkler:
So, we'll keep learning. Dr. States, Dr. Katz, Dr. Gandotra.

Leith J. States:
One quick thought. Improving the quality of diagnostics in treatment, absolutely worthwhile. Prevention, always more than a pound of cure. Me as a preventive medicine physician, I know that. But I think the actual holy grail here for me is restoration, which I think is in reach with appropriate leveraging of what's on the horizon.

Susan Winkler :
Brilliant. Thanks, Dr. States. Dr. Katz?

Elyse Katz:
Can you hear me okay?

Susan Winkler:
Nope. Now we can't hear you.

Elyse Katz:
How about now?

Susan Winkler:
Yeah, speak up and we should be able to.

Elyse Katz:
Okay.

Susan Winkler:
Yes.

Dr. Elise Katz:
All right. I'll speak up. Great. I just have two comments. One, I want to highlight that like others have said, I don't think one drug or one psychotherapy is going to get us where we need to go to help all of the people who are in need for new treatments. I think by working together, by collaborating with our federal government partners, with industry, with the public, that's really how we're going to make progress in really developing and getting drugs out there to treat as many people as we can. It's going to take time, but I am sort of optimistic as well that we're on the cusp of making progress and really understanding PTSD and being able to make an impact.

Susan Winkler:
We look forward to the research that will help us there. Dr. Gandotra and then Dr. Sokolowksa. Dr. G?

Neeraj 'Jim' Gandotra:
Just a couple themes. One would be creativity is going to drive this as well. Creativities not just in drug development, but also modification of the existing evidence-based interventions in particular for the behavioral therapies. I think that is something that communities can lead the way with and certainly then would be collaboration and expansion and amplification of those.

Then the second piece is really related to workforce and understanding that the behavioral health workforce by itself isn't going to tackle this either, not all of it. Collaboration with primary care, community programs, schools, any place where people encounter people is really where we want to see this go. Actually, I think that's what SAMHSA wants to see is that we want to get that information from everywhere because we're going to be able to fund those creative programs.

Susan Winkler:
Excellent. Dr. Sokolowksa?

Marta Sokolowska:
As stated earlier, it's really exciting to hear about the research and development in this space. We are learning about the disorder, we are learning how to treat it and I think this will be really critical for us to be able to reach to the next step to provide new treatments to the patients. This is also the step to collect the information about safety and effectiveness of these treatments because patients with PTSD, as all other patients in US, deserve safe and effective treatments. That we're open for business and we are here committed to review the information as it comes. Thank you very much.

Susan Winkler:
Excellent. Thank you all. I think if I could capture in just a few words I've heard about the importance of creativity, of collaborating, of continuing to learn and to work together not only with federal and other government agencies, but with the private sector and individuals so that we can do more in diagnosis and in treatment and in prevention. Thank you all for joining us to share that and we're going to turn now. Let's thank this panel, and you can even step out of the spotlight, and we will turn to the public comment component.

I mentioned earlier we are going to hear from our remote speakers first. I will introduce each speaker and then list the next speakers in the queue. The heads-up, the first three virtual speakers are Michael

Abrams, Mary Armstrong, and Ron Blake. As Michael, Mary and Ron prepare, I will recap the logistics for this session.

When I announce your name, that's your cue to prepare to speak. Turn on your camera and prepare to unmute your microphone. Our producers will bring you on screen as you are introduced and you will have up to three minutes to comment. If you do not begin speaking within 10 seconds of my turning the virtual stage over to you, we will move to the next commenter. A countdown clock will display on screen showing the time you have remaining and I will come back on screen when you have about 12 to 15 seconds left. If you go over the allotted time, we will mute you and move to the next speaker.

We are now turning to the important part of listening to those of you who have agreed to participate in the public comment and provide those stakeholder comment components. As I mentioned, we have in the queue, Michael Abrams, Mary Armstrong, and Ron Blake. Michael Abrams, if you would come up on, do we have the video ready to show? Excellent. Michael, please proceed.

Stakeholder Comment

Michael Abrams:
Hi. Good afternoon. Can I be heard okay?

Susan Winkler:
You may. Yes, you are.

Michael Abrams:
I'm Dr. Michael Abrams, Senior Researcher with Public Citizen. We are a consumer advocacy organization with a long history of working toward making medical technologies more safe, effective and affordable. PTSD and related anxiety disorders are an important treatment target of modern medicine of course, and we agree that many people with such debilitating illnesses go untreated or are inadequately treated. Such inadequacies are a function of the availability of current treatments and the need for better treatments as well.

Much excitement now exists about psychedelic drug treatments for PTSD, drugs like psilocybin, LSD and MDMA clearly have powerful brain-based effects, but evidence regarding their precise and safe action to enable the treatment of PTSD and related pathologies remain unfulfilled. Thus, the FDA's most recent decision and rejection of the MDMA plus a psychotherapy application, we agree with the FDA's decision in this case. The MDMA application had several problems, all which should be addressed in future trials before the FDA considers any additional psychedelic applications.

First, the unblinding bias must be addressed. FDA scientists reviewing the MDMA application reported that the amount of such bias could not be estimated from the available data provided. Ways to address this bias include the use of competing substances such as niacin, varying doses of MDMA, the use of other stimulating experiences, perhaps vigorous exercise, for example, to create feelings of openness and competency, and comparative arms that involve stabilized doses of antidepressants. Though imperfect, such approaches need to be attempted to at least partially quantify the true effects of any drug if they exist.

Second, these trials must collect data about toxic physiological effects of these drugs, including effects on liver function and other organ systems, and data that is relevant to the addictive potential of such drugs, namely drug induced feelings of euphoria and substance liking. Notably, the FDA and the sponsor disclosed recently that such data was omitted from the MDMA application.

Finally, future trials with psychedelics combined with talk therapies must standardize the therapeutic approach to mitigate the potential for patient abuse and confounding due to therapist or treatment site variability. Moreover, multimodal psychedelic trials should be designed to differentiate the partial effects of the drug and the coupled non-drug intervention. Arguably the most important result from the failed MDMA trial is that both arms, drug and placebo, showed favorable effects, suggesting that intensive talk therapies alone are helpful. Therein lies substantial hope for an approach that should not be ignored. Thank you very much.

Susan Winkler:
Thank you. Our next presenter will be Mary Armstrong. Those in the queue are Ron Blake and Ness Devenot. Mary Armstrong, if you're ready, we are ready to hear from you.

Mary Armstrong:
Hi y'all, how are you? I am Mary Rachel Armstrong, and I was raised with a lot of generational traumas, sexual molestation. There were issues all along my childhood and so at the age of 21, morbidly obese at 305 pounds, I joined therapy and I was in therapy for years and years and years. I was 42 years old when I took off the last of the weight and went in for surgery to look and feel better and I felt pretty bad afterward. After about 90 days, they found out that my sternum had been severed in half and they had to take out part of it and I began to fight with hospitals and insurance companies and realized that something bigger was brewing inside of me, something that was giving me suicidal ideation and things that were not beatable with the standard forms of treatment that I had tried, because I'd tried all the drugs and I'd tried all the therapies.

EMDR, CBT, DBT had it all, and I can tell you point-blank that MDMA, psilocybin and ketamine, they work. Fibromyalgia will be held at bay after six doses of ketamine using the Imperial College London Method. MDMA will give you an open mind and allow you to hold your own memories in your head and reframe a lifetime of trauma. I know it as fact because I am sitting here today. My kids are so glad to have their mom. My husband is so glad to have his husband and I am so darn glad that Rick Doblin and MAPS exist. Maybe there were flaws in that study, but I didn't have time to find out. I had no time left. I was going to end up at the bottom of a bay if I didn't make a decision to do something wild and crazy that I've only done in a clinical setting supervised by professionals.

I would say to you that the best bet you have of curing these veterans, I know as a woman whose chest was cracked open in half, two inches deep, three inches long and an inch and a half wide. I know as someone who has suffered through what I consider to be institutional betrayal, that this can make all the difference in whether someone lives or does not. I thank you for your time.

Susan Winkler:
Thank you, Mary. Our next speaker is Ron Blake in the queue, Ness Devenot and Jesse Gould. Ron Blake, are you here and ready to speak? Ron Blake, your 10 seconds have expired. Let us know if you want to come back in the queue. Ness Devenot, Jesse Gould and Robert Grant. Ness Devenot, and I apologize if I have mispronounced your name, are you here and ready to speak?

Ness Devenot:
Yes.

Susan Winkler:
Excellent. Let's put your video up in the room and let's proceed. Go ahead.

Ness Devenot:
My name is Neshay Devenot and I'm a senior lecturer at Johns Hopkins University with expertise in psychedelic bioethics. I'm also a board member at Symposia, a nonprofit focused on psychedelic harm reduction. Beyond my academic experience, I'm a survivor of complex PTSD, which means that I understand acutely how important it is to find effective treatment options for this life-altering condition. I also recognize that the urgency for treatment options is not a license to lower our standards for research, despite the efforts of industry lobbyists to suggest otherwise.

For years, pharmaceutical companies have funded advocacy organizations as proxies to exert pressure on policymakers. In 2020, the strategy was the focus of a special report in Reuters titled Big Pharma Wages Stealth War on Drug Price Watchdog. In the psychedelics industry, the most prominent advocacy groups have been funded by the Psychedelic Science Funders Collaborative, or PSFC, which also funded the phase three clinical trials of MDMA-assisted therapy conducted by Lykos Therapeutics. Until a few weeks ago, these groups were lobbying the FDA to approve MDMA-assisted therapy. If this campaign had been successful, we could have been months away from scaling a therapy model based on pseudoscience to the most vulnerable demographics in our society.

Although Lykos has chosen not to release the FDA's complete response letter, employees familiar with the letter have shared that the FDA imposed significant new requirements for any future clinical trials. These new guidelines include a requirement that any therapeutic adjunct to the drug's administration be an evidence-based psychotherapy. The FDA's decision led to debates about the role of psychotherapy in psychedelic clinical trials, with many interpreting this as a signal to remove therapy from psychedelic trials altogether.

So far, these debates have overlooked the most significant ethical issue with Lykos' specific psychotherapy. Due to the stigma associated with formerly underground practices, descriptions of this therapy have employed euphemistic language that presented an inaccurate picture of the intervention. This has led to significant misunderstandings among researchers, which explains why the bioethics literature has not yet engaged with the highest risk applications of touch in this therapy.

At its core, MDMA-assisted therapy taught that therapists can telepathically attune to their patient's needs, including when the patient needs to suffer for their healing. This is a scientifically discredited premise that increases the risk of boundary violations. As Dr. Barry Beyerstein has argued, "When people become sick, any promise of a cure is beguiling. As a result, common sense and the willingness to demand evidence are easily supplanted by false hope. In this vulnerable state, the need for critical appraisal of treatment options is more rather than less necessary." Thank you for your attention.

Susan Winkler:
Thank you. Ms. Devenot. I have in the queue Jesse Gould, Robert Grant and Angela Hargrove. Jesse Gould, if you're present with us, we're ready to hear your comments.

Jesse Gould:
Yes, I'm present.

Susan Winkler:
Excellent. Let's put your video up and we will proceed.

Jesse Gould:
Thank you so much everybody. Sorry my internet's been a little bit shoddy today, so if it blinks out, let me know.

Susan Winkler:
That's okay. Go ahead.

Jesse Gould:
My name is Jesse Gould. I'm a former Army Ranger. Three combat deployments to Afghanistan. I'm also the founder of Heroic Hearts Project, which is a nonprofit that's been connecting veterans to treatments similar to this for the last seven or so years. Today I'd say I'm before you disappointed but not surprised. For veterans in this country, that phrase, "disappointed but not surprised" has become too common. When we ask our government for help, when we do everything the right way and then just the burden falls back onto us to figure it out for ourselves, to lead the research, to lead the advocacy, and once again that's happened. It echoes with the FDA's recent decision to delay the approval of MDMA-assisted therapy. Once again, veterans like myself are left in disbelief wondering how many more lives must be lost before action is taken.

For the past seven years, we've been on the front lines of the veteran suicide epidemic, which to date has taken over 150,000 veteran lives and that is more than have died in combat by more than a factor of 15. This is not just a crisis, it's an emergency that demands national attention. While the FDA hesitates, veterans by the thousands are traveling overseas to get life-saving care of the assisted psychedelic therapies. On the outside of this decision, people know that these treatments work. There's countless anecdotal evidence. There is a science there, and so it leaves a lot of us asking why is it so hard to then just get it to some sort of degree of approval? The VA itself is even using MDMA in clinical trials and is an advocate for these going forward and were also disappointed by this decision.

The results speak for themselves. Not conjecture. It's based on years research and real-world results. Let's not forget that when faced with the COVID pandemic, the FDA, the government moved at lightning speed to address this crisis. MDMA-assisted therapy requires a similar sense of urgency, but it is fundamentally different from medications like SSRIs because it relies on the essential combination of MDMA the chemical and psychotherapy. Unfortunately, the current FDA clinical trial criteria are not designed to properly evaluate these sort of beyond the scope treatments. This has already been brought up, the urgency of the veteran community, the need of these treatments. We see that they can be effective, and so we're here just asking how can we move forward? How do we not have to wait many more years and many more veterans dying to get some sort of effective care? Thank you so much.

Susan Winkler:
Thank you Mr. Gould. Our next in the queue we have Robert Grant, Angela Hargrove, and then I understand that Ron Blake is ready. Ron, you are third in the queue. Robert Grant, if you're with us and ready, we are prepared to hear from you.

Robert M. Grant:
Hello, I am Robert M. Grant and I'm a practicing physician, a professor of medicine at the University of California, San Francisco, and a former chief medical officer of a large aid service organization. I've also served on an FDA advisory committee through four new drug applications, including two first in class medications. I led pivotal research on HIV pre-exposure prophylaxis that led to FDA approval in 2012.

I count myself as a friend of the FDA, and as a friend of the FDA, it is my opinion that their recent review of MDMA failed. The FDA failed to provide consistent guidance to industry, failed to stand by guidance they had previously given, and failed to provide essential context for their external advisors. I became trained in MDMA assisted psychotherapy because I'm aware of how PTSD drives enormous suffering on its own and that PTSD is an underlying driver of many medical and surgical diseases.

For example, I work in the intensive care units at a large public hospital in San Francisco. After every shift, I walk around my surgical and medical ICUs and I ask myself, "What proportion of the patients in these medical and surgical ICUs are actually here because of untreated PTSD or undertreated PTSD?" There's many shifts when I leave the hospital knowing that 100% of my patients have PTSD that's been neglected. You can count the ways, substance use disorders, tobacco use disorders, alcohol use, fentanyl, overdoses, trauma due to violence, undiagnosed HIV due to stigma, suicide attempts. It goes on and on. PTSD is a major driver that goes well beyond its psychiatric morbidity.

As I said before, the existing therapies for PTSD have some efficacy, that is clear and that's true, but acceptability is low. I understand that less than 5% of the impacted population is willing to complete existing therapies for PTSD, 5%. That leaves enormous unmet need.

The review of MDMA I think failed. It failed to provide context. I personally found that the use of blinded adherence raters as primary outcomes is rigorous and is a best practice arising from decades of research on how best to blind MDMA trials. I appreciate suggestions that niacin and low dose MDMA or intensive exercise have been helpful for blinding these trials, but these were tried before. There is an evidence base for rejecting all of those as-

Susan Winkler:
Thank you Dr. Grant. Our next speakers in the queue are Angela Hargrove, Ron Blake and Moe Heidaran. Angela Hargrove, if you're with us and ready, we are prepared to hear from you.

Angela Hargrove:
My name is Angela Hargrove and I'm the proud mother of three sons from a small conservative... Decades I've worked in clinical research and mental health. I've built psychedelic research programs and I've collaborated with veterans organizations like Reason for Hope and the Veteran Mental Health Leadership Coalition. I'm here today not just as a professional, but as a wife whose family was saved by psychedelic therapy when all else failed.

My husband, a talented lawyer running his own thriving business, fell into addiction under immense professional pressure. Our once loving home became a stage for despair and multiple traumatic hospitalizations. Despite my connections in mental health and consultations with top psychiatrists, he worsened, becoming someone I no longer recognized. He even experienced a coma two weeks after the birth of our youngest son. Financially and emotionally drained, we turned to psychedelic therapy overseas at Avante Ibogaine Institute under the astute care of Dr. Boda. The transformation was

immediate and astounding. Today, my husband is thriving, a loving father and husband, years into sobriety and mental health stability after just one psychedelic treatment.

While our story isn't solely about PTSD, it underscores psychedelic medicine's potential to heal deep-seeded trauma. As we explore advancing PTSD treatments, I strongly advocate for the consideration of psychedelic-assisted therapies. Research indicates that many struggle with traditional PTSD therapies, whereas psychedelic-assisted treatment offers a novel approach, potentially easing the process of confronting traumatic memories. The impact often transcends our current assessment measures. These are stories of lives and families rebuilt. The urgency of this matter cannot be overstated. As we pursue further research, we must recognize that the risk of inaction is real and devastating. For millions of Americans, including veterans, the status quo just isn't working. It did not work for my family. The risk we took in seeking alternative treatment was far less than the risk of doing nothing.

In our pursuit of comprehensive studies and data, we must not lose sight of the human cost of delay. Inaction means continued suffering for countless individuals and families. The spirit of the Right to Try Act resonates deeply with families like mine. It represents hope for those who have exhausted all of their options. If we could go back, we would take the same risk over and over again. Put simply, our veterans and all those suffering shouldn't have to travel abroad for healing. I hope we can work towards making these innovative treatments available here at home. Thank you so much for your time and consideration.

Susan Winkler:
Thank you Ms. Hargrove. We have in the queue Ron Blake, Moe Heidaran and David Heldreth Jr. Ron Blake, if you're present, we are ready to hear your comment.

Ron Blake:
Yes. My name is Ron Blake. PTSD is like having broken ribs. Nobody can see it, but it hurts every time I breathe. Three men entered my downtown Phoenix loft one night while I was asleep, I was held down, beaten and raped. I represent myself daily as a tenacious survivor, but I've also been speaking out as an advocate for others on my ongoing nine-year cross-country journey to recover from the PTSD and to reach a symbolic goal involving a late-night comedy show. I gave a TEDx talk about how an unexpected moment of laughter from this comedy show stopped me from dying by suicide at 10:44 PM on November 2nd, 2015, sending me out on this now 83,000-mile adventure to learn how to process the trauma and to overcome PTSD.

Along the way, I've met 33,387 individuals, one by one who've opened up to me about how they've been impacted by PTSD. They've each shared their powerful stories in 94 languages with 32 Sharpie marker colors on 508 giant foam boards. It is a massive collective story of struggles, isolation, heartbreak, loneliness, tragedy and nightmares, but it's much more than that. It's an incredible collective story of moxie, optimism and triumph.

I've received medical services for surgery and extensive physical therapy since the trauma. A violent crime victim compensation program assisted me with funding to restore some financial stability after I sustained $110,000 in trauma losses, but it's the PTSD part of my overall recovery that's been the most challenging for me. A team of mental health counselors have worked with me over the years. I've had successes. However, the recovery continues to be a work in progress.

I had a suicide attempt back in May 30th of 2015. Many of the people I've met on my travels from Newark, New Jersey to Yorba Linda, California opened up to me about their own suicide attempts. Scores of other folks shared stories of those we lost to suicide. PTSD is formidable and I am formidable because I have a vibrant army of 33,387 strangers who've got my back, and I've got their backs as well. We are people from all walks of life and all of these individuals hold out hope for the same thing that I do, for additional treatments and viable options for healing to help us move beyond the debilitating injurious impacts of PTSD. Thank you.

Susan Winkler:
Thank you, Mr. Blake. In our queue, we have Moe Heidaran, David Heldreth Jr., and Arash Javanbakht. Moe Heidaran, if you are with us, we are ready to hear from you.

Moe Heidaran:
Thank you so much. Hopefully you can hear me great.

Susan Winkler:
Yes, we can.

Moe Heidaran:
I appreciate the invitation to speak today. My name is Moe Heidaran. I'm a cellular molecular biologist trained at NCI, worked at FDA and I work in several biotech industry as well. I'm here as a representative of Cory Heidaran's Charitable Foundation, CHCF. CHCF mission is to transform how we approach the brain condition with serious and life-threatening behaviors and to prevent, treat and cure this condition like any other physical diseases underscored.

Needless to say, suicide is now becoming number two reason for death in children and young adults. Our veterans have close to double the rates of suicide as compared to general population. The trend is alarming and existing health program(s) to prevent brain condition with serious and life-threatening behavior, including suicide, are not working in my opinion. In addition, our veterans are disproportionately affected by PTSD, as you know. The CHCF mission, as I discussed before, is to transform how we approach brain condition with severe life-threatening behavior, but our vision is to develop the first available FDA-approved diagnostic for early detection of individual at high risk using genetic and epigenomics. Our aspirational goal is to develop the first ever cure-

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curative therapies for serious and life-threatening conditions using genetics and epigenetics. A cumulated data set from several consortiums, one included by Veteran Administration, MVP, as well as PsychENCODE has already provided proof of concept correlating genetic, epigenetic factors to different mental health conditions. We believe due to complexity of mental health diseases being polygenic in nature, like autism spectrum disorder, we need to overcome this complexity and lack of substantial investment in translational research by conducting large size, well-powered observational, longitudinal studies to better correlate genetic , epigenetic factors with serious conditions that are life-threatening. We encourage the community to capitalize on our expanding knowledge of biomarker discovery, genomics, recent advances in genomic editing, gene therapy, to dare imagining the possibility of developing first ever true personalized precision medicine for many of these conditions. Thank you.

Susan Winkler:
Thank you. Our next speakers are David Heldreth, Jr., Arash Javanbakht and Debbie Knight. David, if you are present and with us, we're ready to hear from you.

David Heldreth:
Thank you very much. Good morning for me and good afternoon for the speakers and everyone else present. Thank you for allowing me the time to speak. I'm here with Panacea Plant Sciences, a Washington State biotech company. We're currently studying PTSD and other conditions, and we work heavily with Indigenous peoples, including Native American organizations. The colonization of the United States led to the murder of leaders, taking of children, people were killed for speaking their language, kids were taken to residential schools, religions were banned. This led to generational and communal traumas and PTSD. There are 574 recognized tribes, yet on this panel there's a variety of government agencies but there's no one from the Bureau of Indian Affairs or the Indian Health Services. Why weren't they invited? It seems like a very large oversight. Additionally, there was a small time for turnaround in order to put in to speak to this. Perhaps in the future an outreach to those communities could rectify this and allow for easier access for the community…

Susan Winkler:
Mr. Heldreth will return to you with a minute, 45 seconds if we can return to your signal. So Mr. Heldreth will... Okay. If there's technical challenges virtually, then we pivot and we do things in-person. Allow me to remind those of you who are here in-person to give remarks. And let me first queue you up. We have in order Karen Dunn, Paul Kennedy and Jonathan Lubecky. You'll be the first three. I'm going to step down below and we will use both podiums. When you first hear your name, proceed to the stairs. The second time you hear your name when there's an open podium, please come to the podium. So Karen, come on up and then we will proceed. I will come to the front when you have about 15 seconds left. So again, our queue for in-person is Karen Dunn, Paul Kennedy and Jonathan Lubecky. Karen, if you're ready, please proceed.

Karen Dunn:
Yes. Good afternoon, everyone. My name is Karen Dunn. Thank you for holding this session and thank you for inviting me to speak. Is that better?

Susan Winkler:
Yes.

Karen Dunn:
Again, thank you for inviting me to speak. Thank you again for inviting me to speak. I'm a finance professional. I have a graduate degree in business I'm a finance professional. I have a graduate degree in business administration and I've worked in banking and finance for over 30 years. My hope in speaking here today is to support the FDA's effort to address the dire need for better treatments for PTSD and also to bring awareness to the profound and life-changing potential of several novel therapeutics. My perspective comes both from my lived experience of dealing with PTSD and also is informed by what I've learned facilitating peer support groups. I've experienced firsthand the stunning difference in effectiveness between traditional treatments and also the more recently available novel therapeutics.

I pursued traditional treatments for 30 years. I tried everything. I had access to the best care available at Mass. General Hospital. I worked with excellent providers, and we collaborated. We tried everything and nothing helped. But about five years ago, I learned that Yale was doing a clinical trial for psilocybin for

depression. And I've had terrible experiences with prescribed medications and hold very conservative views on this. I was scared to try it. That said, I can tell you now, this was the best treatment decision I ever made. I was cured. I felt like a new person for about two months. It's hard to describe. My brain just worked better. Unfortunately, the relief didn't last. It felt like the gears in my head just ground to a halt and the stuckness came back. It was difficult to accept that I couldn't continue to access this lifesaving treatment. I felt certain if I had been able to have multiple psilocybin sessions over time, maybe I'd be cured for good.

Still, it was a crucial experience for me to have because it opened my mind to what it actually feels like to feel okay and it motivated me to pursue other novel treatments. Since then, I've been able to access ketamine, Spravato and TMS. And I believe that each of these have contributed to actual healing of old and deeply rooted trauma and allowed me to move forward in a whole new way. I would also like to stress the point that in no way were any of these treatments a one and done situation. It's required multiple sessions combined with lots of skilled therapy. My guess is that these treatments kick off a period of cognitive flexibility and allowed me to literally redo my formative years. Robin Carhart-Harris's snow globe analogy seems spot on to me. And finally, I'd like to share an observation I have made facilitating peer support groups for the past three years. My peers describe a wide variety of diagnoses, depression, bipolar, schizophrenia, substance use, the whole gamut. Peers talk very openly in these groups. And one theme I have consistently heard from almost-

Susan Winkler:
And thank you, Ms. Dunn,

Karen Dunn:
Sorry, peers.

Susan Winkler:
Our speakers in the queue, we'll next hear from Paul Kennedy, then Jonathan Lubecky, and Rogers Masson. So Paul, please proceed.

Paul Kennedy:
Okay. I'm not sure a Kennedy can limit himself to three minutes in an election year, but I'll try. I'm Paul Kennedy. I am a retired Marine that spent 34 years in service. I got out in 2019 as the commanding general of Marine Corps recruiting. In that role, I traveled around the country interacting with applicants and their families, but most importantly, I met a lot of veterans out in the far reaches of this country that had not seen another service member literally since they were discharged, whether that was in Vietnam or the War on Terror. That is a story in and of itself that we don't have contact with these people. 20 years ago today I was returning my battalion from Aramadi, Iraq. A battalion is about 1,000 infantrymen. Over the course of the seven months in that deployment, we experienced a 30% casualty rate. 34 young men were killed in that time. And this is before we even counted TBI and other blast-related injuries as worthy of a Purple Heart. And my guess is that 100% of the battalion would probably have earned that distinction given the severity of combat.

Who were these guys? Well, about 25% of the battalion were high school seniors eight months before they deployed to combat. They didn't expect their lives are going to take a turn that they took and really that they've borne for the last 20 years. In April of this year, I attended a reunion of these veterans in Southern California and they interacted with me for three days very tentatively at first and then they opened up. They brought their families with them. It was almost universal that these veterans had

experienced relationship issues, underemployment, financial issues, substance abuse problems. They couldn't sleep. They were having nightmares. And they weren't complaining to me about this, but they were asking me, "Sir, we served for you under the most extreme conditions. We went home after four years and nobody has been in contact with us since."

This is a crime. We made a promise to these young people that they would be, in our case, Marines for life and that the service would take care of them if they served their country. And yet after four years, 75% of them get out and they go back to wherever they came from and nobody is contacting them and the suicides continue. 21 members of that battalion have taken their lives since they returned, and the statistic says that you're more likely as you age as a veteran to succumb to suicide. And so the numbers are only going to get worse. There are cures out there and we should avail ourselves of the most current technology. The SSRIs that Dr. Fischer was talking about are 25 years old. We can do better than that. FDA, you need to act now.

Susan Winkler:
Thank you, Mr. Kennedy. Our next in the queue, Jonathan Lubecky, Rogers Masson and Juliana Mercer. Mr. Lubecky?

Jonathan Lubecky:
Ladies and gentlemen, my name is Jonathan Lubecky. I served in the Marines and the Army. Eighteen (18) years ago I returned from Iraq with crippling PTSD. 10 years ago I underwent an as-yet-not available treatment, MDMA-assisted therapy. And my VA medical record, as well as my demonstrated actions show that my PTSD is in full remission following just the three-month protocol. I believe I'm living proof of a simple fact, you can heal from PTSD and live a normal life. I underwent this treatment after taking the currently available pharmacological treatments to no effect with horrible side effects, including suicide, which I have been hospitalized for and attempted five times. Although I am healed, I intimately remember what it was like to live that FDA-designated life-threatening condition. While my life is no longer in danger, millions of Americans live daily with the life-threatening mental injury called PTSD.

The last time the FDA approved a pharmacological treatment for PTSD was last century. We have fought two wars, including the longest war in US history, since then. 50,000 Americans take their lives due to suicide every year. Tens of thousands more die from deaths of despair due to PTSD. There's clearly an unmet need as confirmed by the Undersecretary for Health at the VA, Dr. Elnahal. He and those who work at the VA know the cost of PTSD because they get the blame, experience the sorrow and loss first-hand. However, they are limited to only treatments that are approved by the FDA. Were there mistakes made in the recent MDMA-T application considered by the FDA for the treatment that saved my life out of an eagerness to help stem this tide? Yes. However, I do not believe that the millions of Americans who suffer daily with PTSD should pay the price nor should fear and politics paralyze innovation with endless years of long research as Americans with PTSD suffer needlessly. We as a country, the FDA and properly trained medical professionals know how to administer life-saving drugs.

Chemotherapy is highly destructive to the body. Cancer is worse. We use exceptionally powerful narcotics and anesthesia, but surgery saves lives. When one of my guy's foot and ankle were destroyed beyond repair by a roadside bomb, it was amputated. In each of these examples, the condition being treated and its effect on the patient are weighed. While my friend has an amazing prosthetic due to a concerted effort by the government to assist amputees due to combat injuries, those innovations helped all amputees. There isn't a prosthetic for the soul. There is no prosthetic for mental injuries. Why is it that when pharmacological treatments for PTSD and their evaluation, the risk of living with PTSD

was ignored, especially by the advisory committee who wandered into tropes of cocaine use and off-label use of Ozempic? I don't believe this is because you're heartless. It's because you don't understand what it's like to live with crippling PTSD.

The FDA has the statutory authority to restrict any approved medication with strong revs labeling. There are a lot of options that can apply that have been applied to other approved drugs. Where there is a will, there is a way. What I ask is that like those who served you do your job when asked. Do not cower in fear of what if, because I know what happens if this unmet need continues to be ignored. Far too many veterans [inaudible 01:47:05]

Susan Winkler:
Thank you, Mr. Lubecky. And we will continue to Rogers Masson and Juliana Mercer and Vanessa Walker. Mr. Masson, if you would continue?

Jonathan Lubecky:
clearly state that remission for PTSD is possible and that the FDA show a fraction of the honor, courage and commitment shown by the men I deployed with, is do your job for your country. [inaudible 01:47:23].

Susan Winkler:
Mr. Masson, you're ready. You may proceed. Thank you.

Rogers Masson:
Thank you. My name is Rogers and I want to thank you for the opportunity to be here. I'm honored. And I'm a founder and CEO of a startup based in Asheville, North Carolina. I'm a US Army Veteran. I want to thank all of those in the room that raise their hand, Lafe and Bernard that are in here as well, even though you went in the Navy. It's cool. Go Army. I was also a patient in the... What's up? Good? All right. I was also a patient in the FDA trials in the expanded access that used MDMA to treat PTSD. And I did my treatment at the Pearl Psychedelic Institute in Waynesville, North Carolina with Raymond Turpin, Dr. Turpin, and Kim Skelton. And I put my life on hold to be here. I bought a ticket a few days ago and no one asked me to be here, paid my own way. And so yeah, I'm honored. I'm also a member of the MVP program and I have been since 2010. I can't remember where she is, but... Yeah, there she is. So thank you for that. I'm glad to be in that program.

MDMA-assisted therapy saved my life and it greatly enhanced the quality of my life and the life of the people around me and my family and my friends. I spent over a decade in traditional therapy in the VA system with traditional talk therapy and medications. I received fantastic care from the VA. I'm a fan of the VA, although they're an easy target I guess, but... I had great doctors, great treatment, and it helped a great deal. And I just want to push back. I usually stay out of the noise and let the facts fall where they will. I was told by multiple psychologists and psychiatrists that this was incurable at the VA. And I was told also the frustration by these same doctors at two different VAs and everyone I sat in the lobby with, every veteran that I've talked to personally, not hearsay, and every veteran that I serve with that it helps to a point, so...

It helped me a great deal, but it didn't heal anything. And MDMA-assisted therapy healed me. I now have scars instead of wounds. And I don't know how else to put it any better way. I spent 35 years living with nightmares. I haven't had one since then. [gets emotional] Excuse me. So for whatever that's worth, that is a fact. My dad served 20 years on nuclear submarines and told me that of all of his

experiences, peace of mind is the softest pillow. And MDMA-assisted therapy helped me find that peace of mind. Thank you. I'm here until tomorrow if anybody wants to get a coffee.

Susan Winkler:
Thank you, Mr. Masson. In our queue we have Juliana Mercer, Vanessa Walker and Aaron Wolfgang. Ms. Mercer, please proceed.

Juliana Mercer:
Thank you. I'm Juliana Mercer. I'm a Marine Corps veteran and the director of advocacy for Healing Breakthrough. It's with a heavy heart that I'm here today reiterating a grim statistic that is pervasive, tragic and most of all preventable. We have lost over 6,000 veterans to suicide every year since 9/11. According to the VA's numbers, by the end of the year, we'll have lost an estimated 150,000 veterans here on American soil to suicide. To my fellow veterans and I, these are not just numbers. They represent brothers and sisters we individually mourn, carrying each loss's personal and collective pain. Veterans serve this country with honor, but many returned with invisible wounds. While aimed to live meaningful lives in the memory of those we've lost in war, we now face a different battle at home and it's one that we are not winning. Still, we stand firm in our resolve to prevent further loss.

This is not just a policy discussion but a desperate plea for action. The last time the FDA approved a new medication for PTSD was over 20 years ago. Many have debilitating side effects and they fail to help over 40% of patients. Cognitive behavioral therapy can be effective, but it's challenging to complete. And even then, half of those that finish do not find relief. However, after decades of research, we now see hope in psychedelic-assisted therapies, particularly MDMA-assisted therapy. It is important to note that MDMA alone does not treat PTSD. Its success lies in the combination of psychotherapy. This approach backed by years of research provides a supportive environment for individuals to process trauma while minimizing risks. Removing the psychotherapy component would undermine the treatment's effectiveness and could lead insurance companies to deny coverage.

MDMA has shown extraordinary promise, leading the FDA to grant it breakthrough therapy designation in 2017. However, the recent FDA conclusion that the benefits do not outweigh the risk warrants deeper reflection. The delay is harmful to veterans and the millions of others suffering from PTSD who risk suicidal ideation and for some death by suicide. The federal government must explore efforts to accelerate novel treatments for PTSD. In January, the VA funded studies on MDMA and psilocybin-assisted therapy, reflecting a belief that these treatments could offer hope where there was previously despair. The FDA has historically worked closely with drug sponsors to gather necessary data for thorough evaluations. This continued collaboration is critical to balancing innovation with safety. And our shared goal must be to provide every opportunity for those therapies to demonstrate their value in well-regulated environments. While veterans are disproportionately affected, more than 13 million Americans suffer from PTSD.

Susan Winkler:
Thank you, Ms. Mercer. Our final three speakers in the room, Vanessa Walker, Aaron Wolfgang and Deran Young. Ms. Walker?

Vanessa Walker:
Thank you so much for having me. I want to just give a shout-out to Dr. States and start by saying maybe I should go off script, but I don't want to go over time. So I do want to say how important it is that people are willing to come and share their trauma with all of us, and I think that needs to be respected.

And I think peer-to-peer support is really, really important. And I just wanted to acknowledge that. My name is Vanessa Joy Walker and I'm here representing the Depression Bipolar Support Alliance, but more importantly, I am here as a person who has experienced trauma. I'm here to publicly acknowledge how crisis has shaped my life and my mind and how the journey toward recovery has really sucked. I mean, I'm just going to be honest.

I'm a two-time cancer survivor with a BRCA2 mutation. I've experienced abandonment, adoption, betrayal, loss, infertility. I've battled depression and anxiety and suicidal thoughts since I was a young person. I'm here to talk about PTSD and the critical need for trauma-informed care. At age 30 while living in New York City, I was going through a messy divorce and I had endured many years of emotional abuse. I was also a diagnosed with cancer. It was like being dropped into a jungle without preparation or planning. My second diagnosis with cancer came at age 36. By then, I was more aware of my mental health conditions, but it did not prepare me for losing my breasts and my ovaries and going into menopause all within six weeks. The emotional, spiritual, sexual and situational side effects are vast, and they continue.

Surviving survivorship is exhausting and often death feels easier than living. I had no idea that these crises and traumas could lead to PTSD. I thought that that was only for war veterans and violent attack survivors. I didn't want people to think that I was broken or less than. What I didn't know is that we've heard PTSD affects many, many people. According to the US Department of Veterans Affairs, 13 million Americans every year. The National Cancer Institute confirms that cancer survivors like me are at a high risk for post-traumatic stress with symptoms occurring even years after treatment. As an adoptee, I've experienced what some call birth privilege. This is a societal view that prioritizes families which are formed through procreation. This adds another level of stress. Treating trauma is complicated. It has taken years for me to find a combination of medications that help me live my best life. We need to accelerate treatment development for PTSD, including the exploration of psychedelic therapies.

Susan Winkler:
Thank you, Ms. Walker. We'll turn now to Aaron Wolfgang, Deran Young and then we'll return to the virtual commenters with Arash Javanbakht.

Aaron Wolfgang:
Thank you. First like to start by expressing my gratitude to the Reagan-Udall Foundation for posting this important forum. My name is Major Aaron Wolfgang. I currently serve in the US Army as psychiatrist at the Walter Reed National Military Medical Center and as well as an assistant professor at the Uniformed Services University and an adjunct assistant professor at the Yale School of Medicine. I also serve as the novel immersion therapeutic deputy consultant to the Office of the Army Surgeon General. PTSD is prevalent in 48% of the general population, in 4 to 17% of veterans and in 10 to 18% of active duty service members after a deployment. PTSD is the most common psychiatric diagnosis for disability discharge across all branches of the US military. Depending on the service, 14 to 27% of all disability discharge service members have service-connected PTSD with the Army accounting for the greatest proportion of 27%.

When we more closely examine the soldiers who are disability discharged from the Army specifically, we find that PTSD is the most common diagnosis overall, medical or psychiatric. The US military is currently losing thousands of service members each year to PTSD-related disability discharges. Each one of these service members is someone who may have otherwise contributed their invaluable military experience to further strengthen our nation's readiness for the next conflict. Instead, we are prematurely losing

them as casualties to PTSD before the next conflict has even begun. For these reasons, establishing better treatments for PTSD is not only a matter of humanitarianism but also a pressing matter of national security.

Despite over $2 billion of DOD investment in PTSD and related research over the past two decades, the efficacy of our current gold standard treatments has plateaued with only about 12 to 20% of patients achieving true full remission in clinical practice. Our patients desperately need us to look beyond tired paradigms and to have the courage to innovate in uncomfortable yet necessary ways. The cutting edge is the bleeding edge. For all the sacrifice and suffering our service members and veterans endure, we owe it to them to embrace the discomfort of innovation. The paradigm of psychedelic-assisted therapy potentially represents one such avenue of innovation that may present as much promise as it does challenges, but these are challenges that require more research to overcome.

Towards overcoming these challenges and in alignment with Section 723 of the National Defense Authorization Act 2024, the DOD's Congressionally Directed Medical Research Programs, or CDMRP, is now accepting proposals to fund studies of psychedelic-assisted therapy specifically for active duty service members with PTSD or TBI under the Psychedelic Treatment Research Clinical Trial Award. We welcome investigators to apply to what we anticipate will usher in a new era of innovation and hope for service members and their families who need it the most. Thank you.

Susan Winkler:
Thank you, Mr. Wolfgang. And we'll turn now to Deran Young, then we'll return to the Zoom for Arash Javanbakht and Debbie Knight. Ms. Young.

Deran Young:
Yes. Hello. Thank you. My name is Deran Young, pronounced like the Rock Group, Duran Duran. I am a mother, retired captain from the United States Air Force, a licensed therapist and the founder of Black Therapists Rock. Black Therapists Rock is a network of over 30,000 mental health professionals that are dedicated to bringing awareness to racial trauma and other cultural legacy burdens. Through our Heal the Healer program, we have been able to train hundreds of Black therapists in psychedelic-assisted therapy, including MDMA-assisted therapy as breakthrough therapies for trauma-related disorders. MDMA-assisted therapy provides a unique healing opportunity not just for the Black community but for all systemically marginalized populations for which medical mistrust creates a significant barrier between healthcare professionals and the clients or patients that they serve who struggle with isolation and hypervigilance.

Many types of complex trauma are prevalent in the military and in other systemically marginalized communities. During my 18.5 years in the Air Force, I served in roles such as family advocacy officer at or near the border of Texas and Mexico. I served as a sexual assault treatment coordinator right here near where we are at Andrews Air Force Base here in the DC area, and as a suicide prevention program manager in Aviano Air Base, where we often had to fly military members to Germany or other countries to get treatment that they needed. My experience with being a therapist in the military was that I was putting band-aids on bullet wounds every single day. And because of the war on drugs, I believe that McDonald's was food and mushrooms were drugs. I was a completely sober person for most of my life until I retired from the military when I discovered plant medicine.

I believe that the FDA can do a lot to change the legacy of institutional betrayal stemming from instance such as Tuskegee Airmen experiment and many, many more. We want to trust research, healthcare and

medicine. And that will only happen when the voices of the people are prioritized over stigma and politics. Thank you.

Susan Winkler:
Thank you. We'll do a little dance there. Thank you, Deran. With that, we will return to our commenters joining us virtually. In the queue, we have Arash Javanbakht, Debbie Knight and Matthew Kodrin. Arash, if you are present and ready to speak, we are ready to hear from you. Please proceed.

Arash Javanbakht:
Hi. I appreciate all the thoughtful and passionate comments by the panel and the commentators and specifically the message of hope that PTSD is a condition to be treated, is not a plague. It's not the new identity you carry with yourself. That's what I share with my patients. Also, I appreciate the pragmatic approach that some of the speakers had about this condition.

I'm a psychiatrist. I'm founding director of Stress, Trauma and Anxiety Research Clinic at Wayne State University. I'm a clinician and I work with people of different backgrounds of trauma. I work with survivors of torture, human trafficking, refugees, first responders, veterans, civilians, all people who have seen the worse of what humans do to each other. And on the research side, I'm funded by the NIH, DOD, State of Michigan to look at environmental, biological, from epigenetic to environments, factors of risk and resilience among children, refugees, adults, responders. Yesterday I had a police officer, a survivor of sexual assault at work, at my clinic, and I was talking to her and working. A while ago after one year of being in treatment her-

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Arash Javanbakht:
[inaudible 02:04:00] challenge was that she had to do grocery shopping online. I believe one of the issues that has been missing from our treatments, and approaches to treatment and evaluation of treatments has been functioning. Look at nightmares and flashbacks on how treatments reduce those, but we are missing out on a person's ability to go out and function.

Now veterans, first responders, others who have been treated for a year or years in psychotherapy or psychopharmacology, might have less nightmares and flashbacks, but still cannot function out there. And their housebound, they cannot even go to their kids' games. They cannot go to a restaurant, they cannot go to grocery store, and I think we need to redirect and focus a little bit more on the functioning. That is why on my side, in our lab, we have been focusing on utilizing mixed reality technologies, artificial intelligence where I give you a pair of glasses, like glasses [inaudible 02:04:57] if you are wearing.

And the patient will find themselves in a grocery store, at a restaurant, at a bar, at house party in the company of their therapist, and they can walk around and interact with these digital human characters who are talking to them and walking around and helping us. The therapists bring the world out there in their clinic and help the patients. This patient yesterday, she came several times, she said, "I want to go to grocery store, do the grocery store treatment." And yesterday she said, "Thank you. I'm saving a lot of money on grocery shopping." This was my message of hope, and I'm hoping that we can redirect some of our attention to the real world functioning and implication of what we do outside in the real world and community outside of what we do in the academia and the papers we publish. Thank you.

Susan Winkler:
Thank you, Mr. Javanbakht. We have Debbie Knight, Matthew Kodrin and Verna Little. Ms. Knight, if you are present, we are ready to hear from you. Please proceed.

Debbie Knight:
Thank you very much. Prevention, education, and collaboration are the components and the basis of my platform today. I appreciate the opportunity to speak with you very much. I'm going to twist this up just a little bit because I am a clinician, so I'm an advocate for patients. I have a heart for veterans, as I'll explain in just a moment. I am an educator. I have a heart for my students, and I see on a daily basis that healthcare clinicians, workers and students are often overlooked in the PTSD that absolutely occurs and a very high percentage of those individuals. So I am advocating that we, not only find these solutions together in a collaborative manner, but that we also implement them into the curriculum. So I'm going to back up now and give just a little bit of background on both a personal and professional perspective so that you'll know where I'm coming from.

I have a doctor of pharmacy degree. I've completed a pharmacy practice residency and then went straight into a clinical position with a general surgery team at the McClellan Little Rock VA in Arkansas. That was a wonderful opportunity and that's where I learned and was immersed in interprofessional collaborative practice. I'm a firm believer in that. I've been precepting and teaching students of all different health professions, primarily pharmacy and medical until the last 12 years, and my current position is one that is absolutely focused on interprofessional education and collaborative practice. So I am a champion of that. I believe in collaboration. I know that it works. From a personal perspective, I have been diagnosed with PTSD. It started in childhood. I had some experience as in adolescence in my adult life and in the healthcare setting. I personally assisted with some very severe accidents and had absolutely nowhere to turn as a resident, a very young and impressionable resident.

You don't think of pharmacists necessarily is the people in the front lines? Well, it depends on what domain that you decide to go into, and I saw my first patient die right in front of me, didn't understand why I kept having nightmares over, and over, and over. There was no outlet. So I am advocating today that we as healthcare workers get rid of that taboo of that stigma that we also don't suffer from PTSD, and I want to bring that awareness to the forefront. Research has shown that 18-48% of healthcare workers suffer from PTSD. That's much higher than the average population, and I just want to again reiterate that I think it's imperative to incorporate self-care into both our health sciences curriculum and into accreditation standards for our healthcare organizations. Thank you.

Susan Winkler:
Thank you. Ms. Knight. Our queue is now Matthew Kodrin, Verna Little and Raj Mera. Matthew Kodrin, if you are present and with us, we're ready for you to proceed.

Matthew Kodrin:
Yes, thank you. So thanks to the organizers, panelists, and speakers only have three minutes, so I'll get right to it. The gear skull doesn't give it away. I'm from South Louisiana. My experience with PTSD started with Hurricane Katrina and it really took hold with a 17-month deployment to Afghanistan as a paratrooper and just numerous other traumas that just followed me over my life. The sense of dread and helplessness that could happen with any sudden trigger made my life just okay at best and absolutely intolerable at its worst. I spent a decade trying every therapy, every medication, reading every self-help book, exercising, doing yoga, meditating, living a healthy lifestyle. Anything I could do or anything I could find to help reduce my symptoms, I did. A decade of work, that's over 5,000 pills, almost

a 1,000 hours of seeing 25 different therapists and doctors over a 100 books and just an insane amount of time, money, energy, effort, and despair. Because no matter how much effort I put into it or how disciplined I was, I can only stop things from getting worse. I could not make them better.

I was lucky because I was accepted into the MDMA Assisted Therapy Drug Trial and from January to March of 2020, three months, a knot I didn't even know I had was unwound inside my chest and a switch flipped in my brain and my whole world changed. I was able to completely alleviate all my PTSD symptoms and I felt like I was gifted my life back. Three months for a life changing breakthrough. To put that in perspective, three months is how long it took the CFI responded to a new antidepressant. Or if I could tolerate the numerous side effects, which according to the FDA is also an increase in the suicidal ideation. Three months is also how long it takes to warm up to new therapists before I can expect clinically significant improvements. The MDMA assisted therapy treatment gave me the tools not only [inaudible 02:11:05] my past traumas, but that I carried around unresolved for over 10 years, but also protected me from new ones.

Since 2020, I've experienced five instances of gun violence and a major hurricane with no stress injuries, a feat that I could not even have fathomed four years ago. It's profound how much of a difference this treatment made in my life and the quality of my life, but not just in my life, but those around me has gone up beyond measure. I know I could be an outlier, I could be just the best case scenario for the existing sample for the drug trial. But if this treatment can have this kind of impact on me, someone that tried everything else before it, then it has to be able to help others who also endured the same kind of traumas and the same kind of problems and seeking treatment. And if it could have... Excuse me. I can't fathom how many lives would be saved if we actually approved this and moved it forward and made it available to those that can help and spent the time identifying people that it could help. Thank you.

Susan Winkler:
[Inaudible 02:12:05] Little, Raj Mehra and Sonya Patrick. Virna Little, if you are present and with us, please proceed.

Virna Little:
Yes. Hi. Good afternoon and thank you for the opportunity to speak. My name is Virna Little. I'm a behavioral health clinician and a national advocate. And I actually wanted to bring up the collaborative care codes and the collaborative care model, which is an evidence-based model to identify and treat behavioral health conditions in primary care settings. There's lots of evidence out there supporting it and mounting evidence, supporting it for the use of PTSD care and treatment and primary care settings. Which I really think is incredibly important to engage primary care as this is where many people go first to be able to seek care and treatment, particularly in communities that may lack a lot of behavioral health resources. In 2017, CMS passed dedicated CPT codes for collaborative care [cites codes] 99492493 and 494. They are now adopted in 34 states on the Medicaid fee schedule and recognized by most commercial payers.

So for a majority of states, this is service that could be provided across the payer mix. There's currently a large trial going on to really continue to gain data and evidence around this model. For PTSD, the Spirit trial was the original one, and so I think it's important for us to really think about things that are already in existence that are available and could be helpful to large populations of people and particularly engaging primary care. There are opportunities now to get particular technical assistance and the ability to advance collaborative care across many of the states funded by SAMHSA, thank you, and recently announced. So I would really just encourage people to investigate the collaborative care codes for their

systems, for their states and to reach out to the organizations that are supporting the ability to adopt and spread this model. So, thank you and I appreciate your time.

Susan Winkler:
Ms. Little. We have Raj Mehra, Sonya Patrick and Debbie Plotnick. Raj, if you are present and ready to proceed, we're ready to hear from you.

Raj Mehra:
I am indeed, so thank you so much. Good afternoon all. I'm the founder and CEO of Celus Therapeutics. We are a drug development company working to advance treatment for several neurological disorders like PTSD, major depression and suicidality. We'd like to kindly request the panel and the FDA to consider providing a pathway for accelerated approval of drugs and PTSD similar to what has been done in oncology and gene therapy indications such as DMD. Where broad labels and approvals for treatment have been provided before completion of all the clinical trials, specifically the PTSD where there have been no approved drugs for the last two decades. It might be reasonable for the FDA and the panel to consider pathways to provide accelerated approval based on a large single clinical trial, but significant benefit. The examples of the 1998 guidance and approval for one large trial is open to different interpretations in terms of level of significance needed for approval.

It would be helpful to have specific guidance document for PTSD TSD trials like what has happened for ALS or Alzheimer's disease to help provide streamlined pathways for broader approval in veterans and non-veterans alike. In this context, I would like to thank the Department of Defense and the large platform trial that they are conducting currently for PTSD to seek new drugs. The trial is called the Military and Veterans PTSD Adaptive Platform Clinical Trial or M-PACT in short, and the website is ptsdclinicaltrial.org. The M-PACT platform will be testing a total of four drugs, including our drug, the intranasal racemic ketamine in an FDA-regulated phase 2 master protocol. Importantly, the study has incorporated different types of biomarker collection as well as a breadth of clinical assessments to tease apart PTSD's heterogeneity and is intended to lead to a precision medicine approach to treatment where the drugs will be prescribed to our service men and women based on what is likely to be most effective for them.

But this precision medicine approach, we hope to learn and confirm what we know and what we don't know about PTSD to drive future drug development. To find out more about this trial, please go to our study website ptsdclinicaltrial.org, where patients can express interest in enrolling in this study. Interested industry partners can respond to a request for information and entities interested in participating as a clinical site can reach out to us. In conclusion, we'd like to thank the division of psychiatry for the continued excellent guidance and to consider providing regulatory pathway for a large well-conducted PTSD study such as under the tutelage of the MPACT trial platform to have a shot at being able to apply for accelerated approval pathway for the broader population in veterans and non-veterans alike. Thank you again for the invitation.

Susan Winkler:
Thank you, Mr. Mera. We have Sonia Patrick, Debbie Plotnick, and Jessica Punzo. Sonia, I see you. We're ready to hear from you. Please proceed.

Sonja Patrick:
Okay. Greetings everyone. Thank you for allowing me to speak. My name's Sonja Patrick. I'm in Michigan and I think that I'm going to have a different viewpoint of this than the majority. When I got out in 2005,

I was hurt pretty bad in Iraq, so I was in a wheelchair for 16 [inaudible 02:18:08] years and the VA, they only pushed medication on me. So I listened to my doctor. I was 20 years old. I thought he knew everything and he would prescribe a hydrocodone and it got to the point he just keep increasing my dosage to where I was taking 120 pills a month. I've never been a drug addict. I barely smoked pot my entire life, but all of a sudden, I was taking this for pain management and then one day they just took it all. And when that happened, I became very sick. My mental health went down worse than ever before.

And so my concern with this, the psychedelics, is I do agree that we need to continue research and move forward, but what happens in a few years when they decide to, it's not good for us overall, and then they take it and put a bunch of veterans in the same situation. Because I heard a panelist earlier saying that, "We're learning, we're moving forward." It's great that everyone's learning, but in the end, it's the veterans that are the ones that are suffering when you just yank it from them like that. So I hope that makes sense. I guess that's pretty much all I have. I won't take more of your time. Just as you're doing the research into the good qualities of this, please try and consider the outcome in the event that you have to take it away. So, thank you.

Susan Winkler:
Thank you, Ms. Patrick. We have in the queue, Debbie Plotnick, Jessica Punzo and Ashley Troxell. Ms. Plotnick, I see you and we are ready to hear from you. Please proceed.

Debbie Plotnick:
Thank you. I am an executive vice president at Mental Health America, MHA. And at MHA, we have observed listened to what people who have mental health conditions have experienced for over 115 years. We do so through our national office and our 143 affiliates. We carefully listen and observe what policymakers are and legislators, scientists and clinicians also say, and what they show us about how they perceive people we represent. Unfortunately, it is often dismissive, disrespectful, and disparaging. MHA recently shared with the FDA diverse examples of lived experience of PTSD, not just veterans. What we and other people have heard is that PTSD has as many causes as there are people who are affected, but what has become clear is rather than being a disease caused by a pathogen, it's the result of something happening. Could be an injury, could be an illness, something terrible. Injuries often are sudden, such as traumatic accident or shooting.

They may occur over time much like a stress fracture. This can be due to environments such as domestic violence or childhood abuse. Other long-term stressors involve systemic discrimination such as racism and homophobia, bullying or living in communities where violence is endemic. You heard from Dr. Fisher and others about the treatments currently offered and about their low efficacy and iatrogenic effects. Now we all know, and we're hearing that people often try to alleviate their pain through the misuse of alcohol or opioids. Some also seek out, use medicinal substances that are officially considered to have no clinical value, but have provided a path to healing for many.

People report these medicinal substances have helped decrease fear, allow them to explore causes of their trauma and soothe the challenges of processing difficult emotions. One of our people at our listening session said MDMA changed his life. Presently, people are willing to risk the dangers of using unregulated possibly adulterated street drugs or traveling to foreign countries to obtain relief. What is harder to mitigate than people's pain and we're disconcerting, are commonly expressed attitudes surrounding PTSD. Some decision makers still dismiss PTSD sufferers altogether. We've heard clinicians still regard PTSD as a made-up ailment, and people are asked what you did to provoke abusers or attackers, MHA implores decision makers to check their prejudices and put politics aside. Thank you.

Susan Winkler:
Thank you, Ms Plotnick. Our next speakers will be Jessica Punzo, Ashley Troxell and Barry Walden. Jessica Punzo, if you are present and prepared to proceed, we're ready to hear from you-

Jessica Punzo:
[inaudible 02:23:13]. Can you hear me?

Susan Winkler:
Excellent. Yes, we can hear you. Please proceed.

Jessica Punzo:
Okay, great. Thank you so much. Good afternoon everyone, and thank you for having me today. My name is Dr. Jessica Punzo, and I'm a licensed clinical psychologist and the president-elect of the 56th division of the American Psychological Association focusing on trauma psychology. I want to acknowledge that the opinions I express today are solely my own and do not express the views or opinions of American Psychological Association or their division of trauma psychology. It is a great honor to be able to be a part of this discussion on advancements of trauma-focused interventions for PTSD. Three minutes is such a short time to express my thoughts on such an important and complex topic, so instead of filling that time with a bunch of statistics and data, I want to speak from my heart and my lived experience as a front-line trauma psychologist who has been practicing for almost 15 years. I've worked in a wide variety of settings, treating trauma from prisons to jails, to community mental health centers, to the VA and various other outpatient settings. I've worked with all types of survivors with various different traumatic experiences and symptom presentations. I have been trained in and utilized various evidence-based treatments for PTSD, and while these treatments can be very helpful, the reality is that not all individuals will respond to these types of treatments, and the harsher reality is that many survivors will continue to die by suicide due to their PTSD. Unfortunately, sometimes traditional therapy is just not enough to break through years of PTSD symptoms or stuck traumatic content. Moreover, the few medications that have been approved to treat PTSD only treat a small portion of the symptoms leaving the vast majority of PTSD symptoms unresolved. In my private practice, I typically see clients who have complex trauma histories and don't fit neatly into the DSM-5 criteria of PTSD.

These clients have often experience years of childhood abuse and neglect that gets compounded by trauma and adulthood. Years upon years of this compounded abuse simply cannot be solved in 12 sessions. As Dr. Judith Herman wrote, "Complex trauma requires complex treatment," and the unfortunate reality is that many clients with trauma histories have experienced multiple failed treatments and are desperate for new treatment options. Therefore, we really need to think outside of the box and reimagine what comprehensive trauma therapy can look like. We need to be open to continue exploring novel and promising approaches, one of those being psychedelic-assisted therapies. I personally got trained in psychedelic-assisted therapy because I wanted to offer another option to my trauma clients.

Psychedelics have the opportunity to enhance, assist, and accelerate already empirically supported treatments for trauma. We also need to be more strategic on how to make these type of treatments or research participation in these studies more accessible to all trauma clients. I believe that with proper training and oversight, psychedelic-assisted therapy has the potential to change the field of trauma psychology and how we treat PTSD. Bottom line is that trauma survivors deserve better. They deserve more than we've given and they deserve hope. As providers, researchers, government officials, and

policy makers, we have a responsibility to do our part in advancing new and promising treatments for them. Thank you so much.

Susan Winkler:
Thank you, Ms. Punzo. Our final three speakers are Ashley Troxell, Barry Walden, and Alan Wiederhold. Ashley Troxell, I see you. We are prepared to hear from you. Please proceed.

Ashley Troxell:
Thank you. I'm grateful for the opportunity to offer public comment. My name is Ashley Troxell and I'm representing myself. I've earned my MS in teaching and learning and am an active member of the Denver Colorado community where psychedelic mushrooms were decriminalized in 2019. My personal use of psilocybin mushrooms along with my experiences as a natural medicine advocate, educator, and facilitator have transformed my life, especially with the support of my community in helping me overcome PTSD. Today, I'm here to advocate for the FDA to recommend the de-scheduling of psilocybin mushrooms and to the DEA and to propose an evidence-based regulatory framework that ensures safe, affordable access. Psilocybin mushrooms boast the highest safety profile of any psychedelic and their potential for treating PTSD is supported by a growing body of research, a 2010 study in the lands that demonstrates that alcohol, tobacco, and cannabis are more harmful than psilocybin. Unlike these regulated substances, psilocybin is non-addictive and carries a low potential for harm with virtually no risk of lethal overdose.

Since the decriminalization of mushrooms in Denver and subsequent passing of the Natural Medicine Health Act in 2022, making growing, gifting and sharing psilocybin mushrooms lawful in the state of Colorado, Denver has closely monitored the impact. At the review panel's meeting in January 2024, law enforcement and health officials reported zero adverse incidents related to expanded access. This significant outcome demonstrates that community use can be both safe and beneficial without overregulation. Despite this safety, psilocybin remains classified as a schedule one substance. This outdated classification prevents people who could benefit from psilocybin from accessing it safely and legally. Oregon and Colorado's 2025 framework for facilitation and clinical therapy presents significant barriers. These models impose excessive fees on providers driving up the cost for sessions, making them unaffordable for most. One microdose session costs several 100 dollars while a full therapeutic dose can exceed $2000.

The support and access I received in my community for free would cost over $200,000 under Colorado's new regulations. Subsequent legislation in Colorado handed regulatory control to an unelected governor-appointed advisory board with ties to the Healing Advocacy Fund, the lobbying wing of the new approach PAC. The reported conflicts of interest and legal lobbying practices are especially troubling when considering the needs of the veterans with PTSD who were supposed to benefit from the NMHA. A study by CU Denver highlights that this model is set to fail BIPOC communities and low-income individuals, Oregon and Colorado should serve as lessons on how not to proceed. I implore the FDA and federal agencies to advance options for the treatment of PTSD that prioritize the health and well-being of the American people over corporate profits. Thank you for time and consideration. I look forward to questions.

Susan Winkler:
Thank you, Ms. Troxell. Next two speakers, Barry Walden and Alan Wiederhold. Barry Walden, are you with us? And if so, we're ready to hear from you. We will move on from Barry Walden and hear from our final scheduled speaker, Alan Wiederhold. Excellent. We see you. You may proceed.

Alan Wieterhold:
[inaudible 02:29:59] last one picked. Always the last one picked.

Susan Winkler:
As a Winkler, I fully understand. Go ahead.

Alan Wiederhold:
Good afternoon, everybody. I just wanted to echo the sentiments of everyone who has had conversations today. My name is Alan Wiederhold. I'm a multi-generational veteran, business owner with 30 years in the healthcare industry as an insurance payer, and I'm also a survivor of PTSD that actually started at childhood and further as a result of the Gulf War. Through my personal and professional journey, I've come to deeply understand the toll that trauma takes, not just on veterans, but for countless of other individuals suffering from depression, anxiety, and the crushing weight of PTSD. For years, we've seen traditional treatments fall short for many who desperately need relief. As an ultra runner and an iron triathlete, I can tell you that exercise does not always make you happy, but like many others, I found healing and restoration in the most unexpected, crazy place. In MDMA-assisted therapy. MDMA has the ability to open doors to parts of the mind that for many have been closed off due to trauma.

It allows individuals to approach their pain with a sense of safety and understanding that traditional methods don't always provide. It's my own psychedelic-assisted therapy experience that has been nothing short of transformational. It's allowed me to not only process the deeply rooted trauma that I carried, but it allowed me to emerge in that journey with a renewed sense of peace and purpose. Creating a new company that focuses on brain health. My story is not unique. The growing research on MDMA's potential to treat PTSD is showing remarkable results. We've reached a pivotal moment in mental health where the science of neuroplasticity healing power of psychedelics in the therapeutic intervention are all intersecting in ways that we can fundamentally shift how we treat trauma.
Is not just one therapy. It's just a broader conversation that we need to continue to have. We cannot afford to halt progress and let fear of the unknown stop us from exploring what lifesaving treatments could have for millions. MDMA-assisted therapy isn't a miracle cure for everyone, but it is for a lot. It's been key to unlocking healing that traditional treatments just don't. That's why today I ask that we continue these conversations and let the data speak for itself and emerge in these trials and continue these conversation. Thank you and Go Navy.

Susan Winkler:
Thank you, Mr. Wiederhold. With that, we have finished the public comment period. I'll note that the virtual commenter who was interrupted with the technology issue chose not to return to the virtual stage, so that opportunity was provided.

I have to just say thank you to each of today's contributors. Your insights and personal stories are valuable, and we are so grateful for your willingness to share them publicly. And I hope that each of you who joined in person or virtually has learned something today. Maybe you heard something you expected to hear, maybe heard something that surprised you, but I hope you heard something that gives you a bit of optimism that we are doing something, that there are efforts to advance prevention, diagnosis, and treatment of post-traumatic stress disorder.

For those of you who did not have time to comment today, I will remind you that you may submit written comments and email those to PTSD@reganudall.org. There is not a three-minute limit, but you

might think about something fewer than 30 pages. On behalf of our federal partners, we so appreciate you joining us and contributing to the discussion. Watch for the meeting reporting and transcript to be posted at reaganudall.org late next week, and thank you. Have an excellent Friday.

PART 5 OF 5 ENDS [02:34:11]